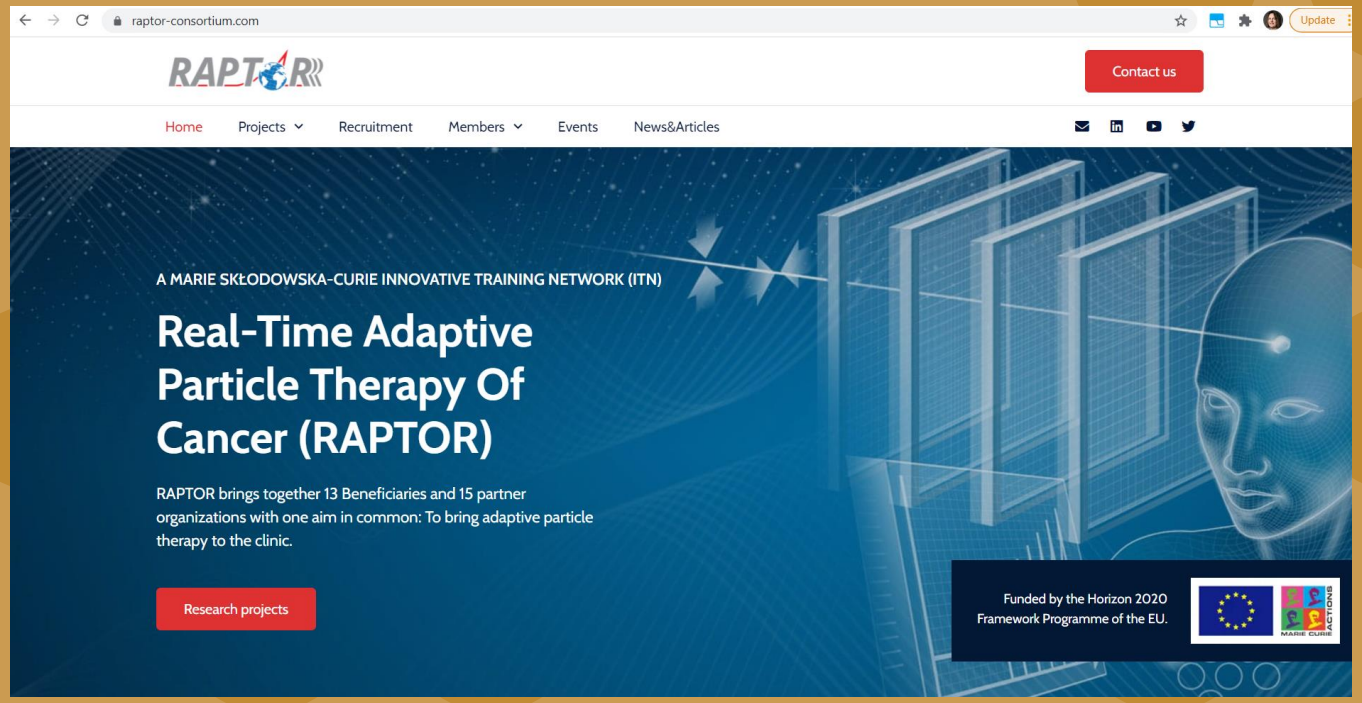
Good Scientific Practice

Stine Korreman
Danish Center for Particle Therapy
Aarhus University Hospital



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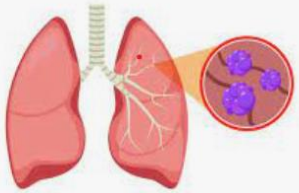
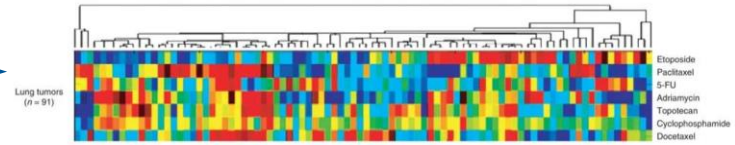
Genome-Guided Adjuvant Cisplatin With Either Vinorelbine or Pemetrexed for Early Stage Non-Small Cell Lung Cancer

Tumour resection

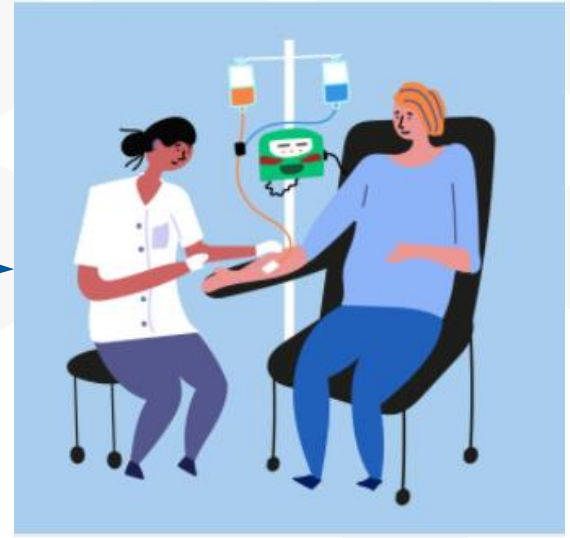


Genomic profiling



Choice of treatment arm

Arms
Experimental: A Resected tumor will be used for genomic expression profiling. Patients with a genomic expression pattern suggestive of vinorelbine sensitivity will be given cisplatin+vinorelbine.
Experimental: B Resected tumor will be used for genomic expression profiling. Patients with a genomic expression pattern suggestive of pemetrexed sensitivity will be given cisplatin+pemetrexed.



U.S. National Library of Medicine

ClinicalTrials.gov archive

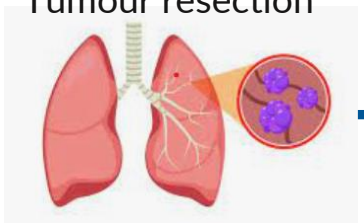
N Engl J Med. 2006 Aug 10;355(6):570-80. doi: 10.1056/NEJMoa060467.

A genomic strategy to refine prognosis in early-stage non-small-cell lung cancer

Anil Potti [1], Sayan Mukherjee, Rebecca Petersen, Holly K Dressman, Andrea Bild, Jason Koontz, Robert Kratzke, Mark A Watson, Michael Kelley, Geoffrey S Ginsburg, Mike West, David H Harpole Jr, Joseph R Nevins

Recruitment started 2007:

Tumour resection



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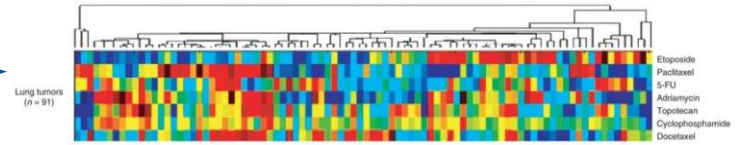

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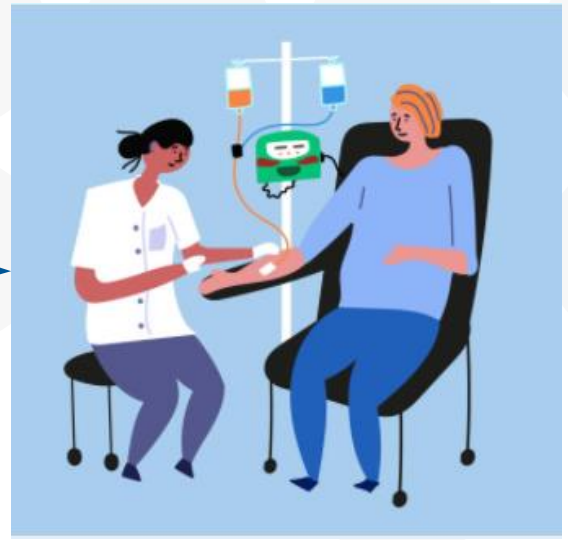

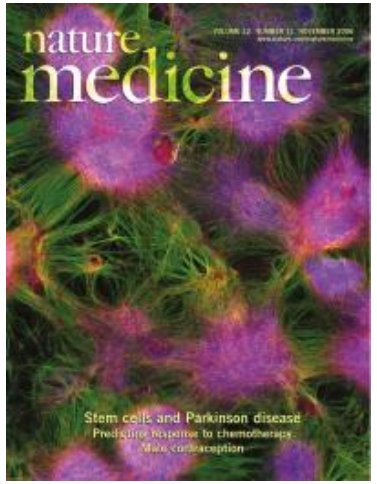

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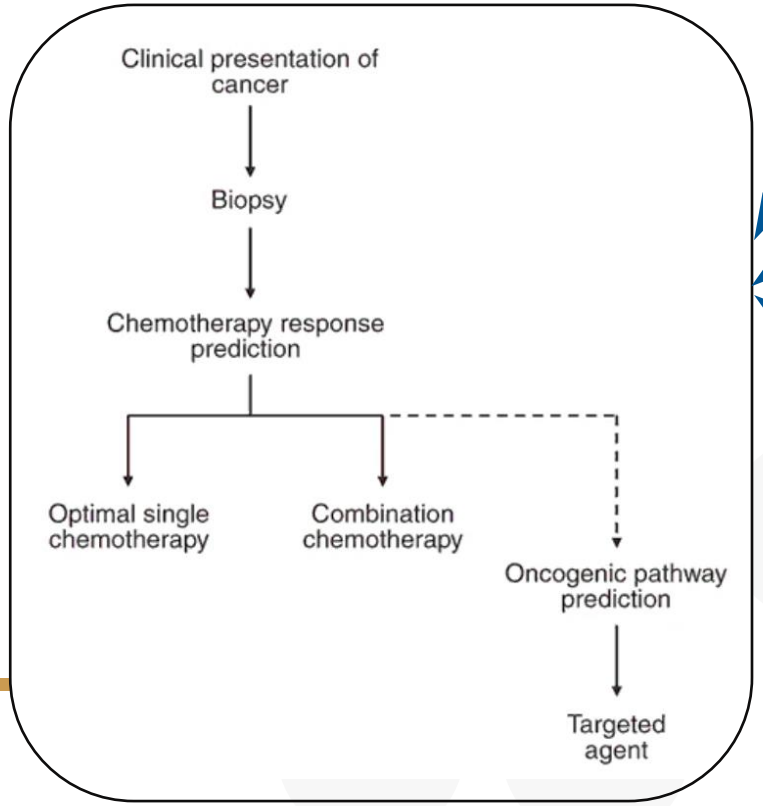
Published: 22 October 2006

Genomic signatures to guide the use of chemotherapeutics

Anil Potti, Holly K Dressman, Andrea Bild, Richard F Riedel, Gina Chan, Robyn Sayer, Janiel Cragun, Hope Cottrill, Michael J Kelley, Rebecca Petersen, David Harpole, Jeffrey Marks, Andrew Berchuck, Geoffrey S Ginsburg, Phillip Febbo, Johnathan Lancaster & Joseph R Nevins

Nature Medicine **12**, 1294–1300 (2006) | Cite this article



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J Clin Oncol. 2007 Feb 10;25(5):517-25. doi: 10.1200/JCO.2006.06.3743.

An integrated genomic-based approach to individualized treatment of patients with advanced-stage ovarian cancer

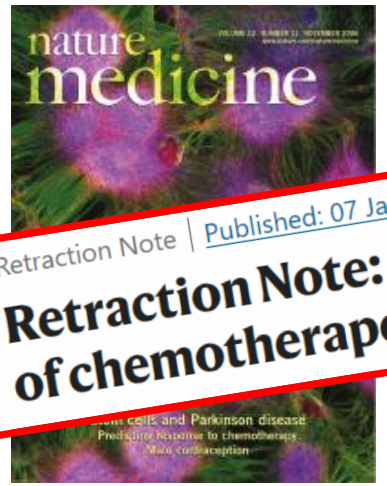
Holly K Dressman [1], Andrew Berchuck, Gina Chan, Jun Zhai, Andrea Bild, Robyn Sayer, Janiel Cragun, Jennifer Clarke, Regina S Whitaker, Lihua Li, Jonathan Gray, Jeffrey Marks, Geoffrey S Ginsburg, Anil Potti, Mike West, Joseph R Nevins, Johnathan M Lancaster

PLOS ONE

PLoS One. 2008; 3(4): e1908. PMCID: PMC2270912
Published online 2008 Apr 2. doi: 10.1371/journal.pone.0001908 PMID: 18382681

An Integrated Approach to the Prediction of Chemotherapeutic Response in Patients with Breast Cancer

Kelly H. Salter, [1] Chaitanya R. Acharya, [1] Kelli S. Walters, [1] Richard Redman, [1,2] Ariel Anguiano, [1,2] Katherine S. Garman, [1,2] Carey K. Anders, [1,2] Sayan Mukherjee, [1,3] Holly K. Dressman, [1] William T. Barry, [1,3] Kelly P. Marcom, [2] John Olson, [1,4] Joseph R. Nevins, [1] and Anil Potti [1,2,*]



nature medicine

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Retraction Note | Published: 07 January 2011

Retraction Note: Genomic signatures to guide the use of chemotherapeutics

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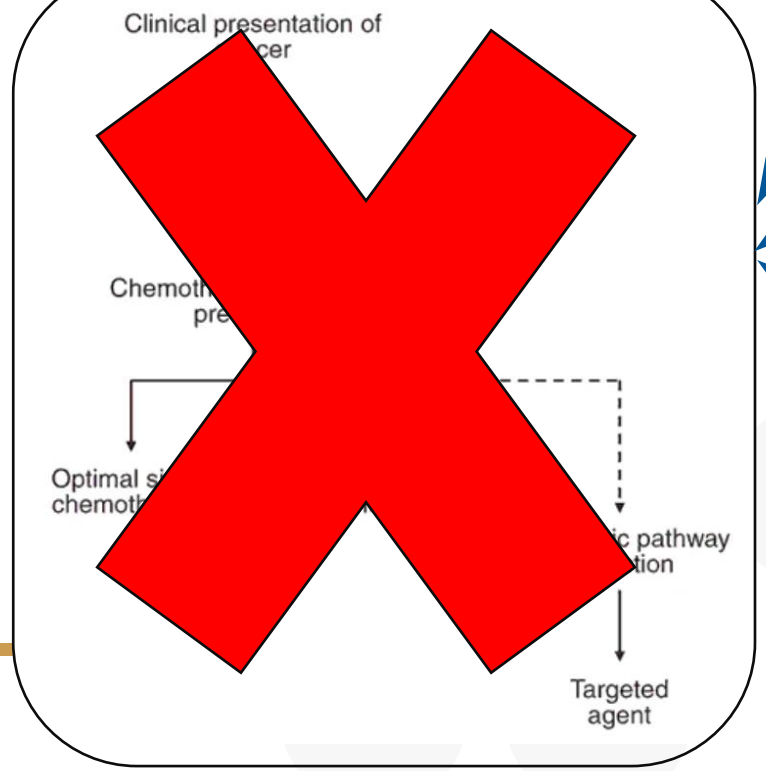

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PLOS ONE

Retraction of Publication

J Clin Oncol. 2012 Feb 20;30(6):678. doi: 10.1200/jco.2012.42.0331.

Retraction. An integrated genomic-based approach to individualized treatment of patients with advanced-stage ovarian cancer

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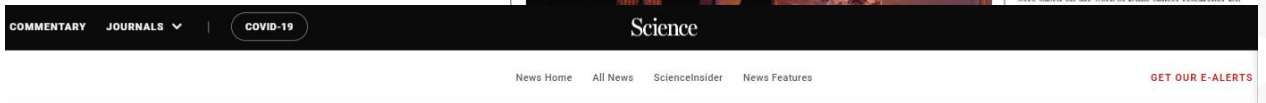
This was a case of research misconduct

- Other labs could not reproduce similar results
- Statisticians found errors in analysis
- Student resigned and raised concerns regarding validity
- Fraudulent claims were found in researchers CV
- Multiple scientists report and publish concerns regarding data and analysis
- Clinical trials were stopped
- Papers were retracted



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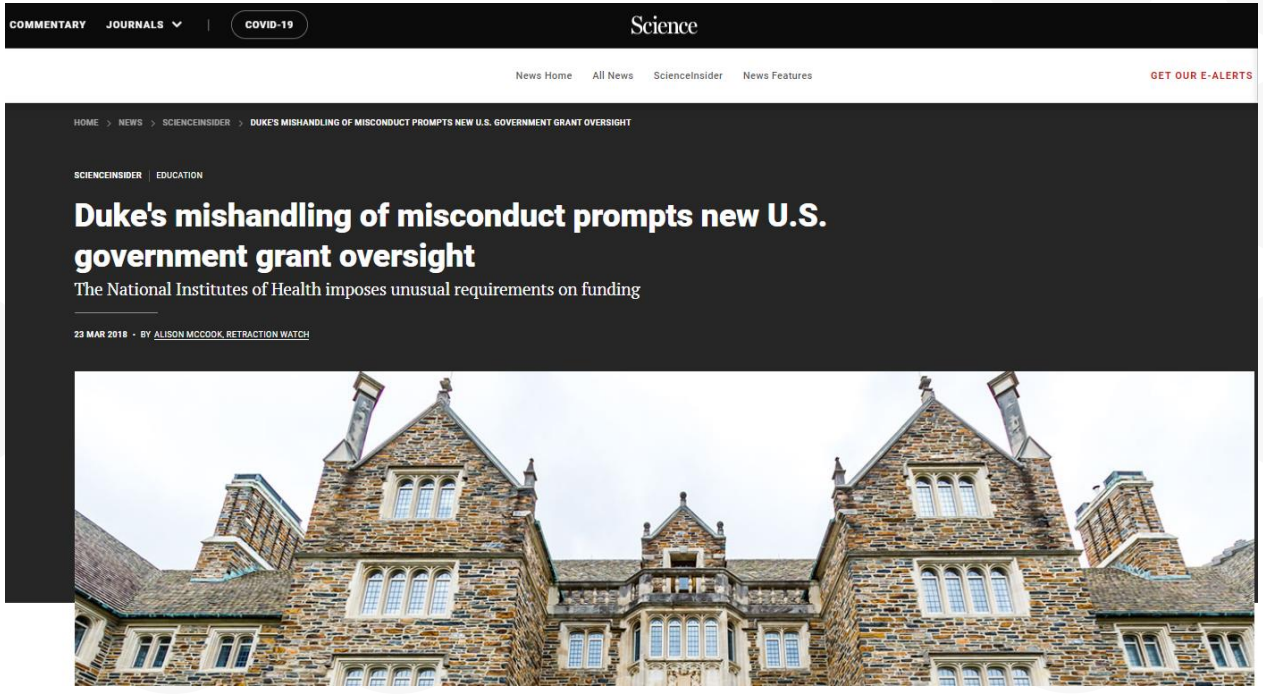
DCPT

Research misconduct affects real life

- **Patients are treated based on false evidence**

- Research progress is hampered or delayed
- Trust in research is reduced – both within research community and in the general public
- Access to research funding may be restricted
- …



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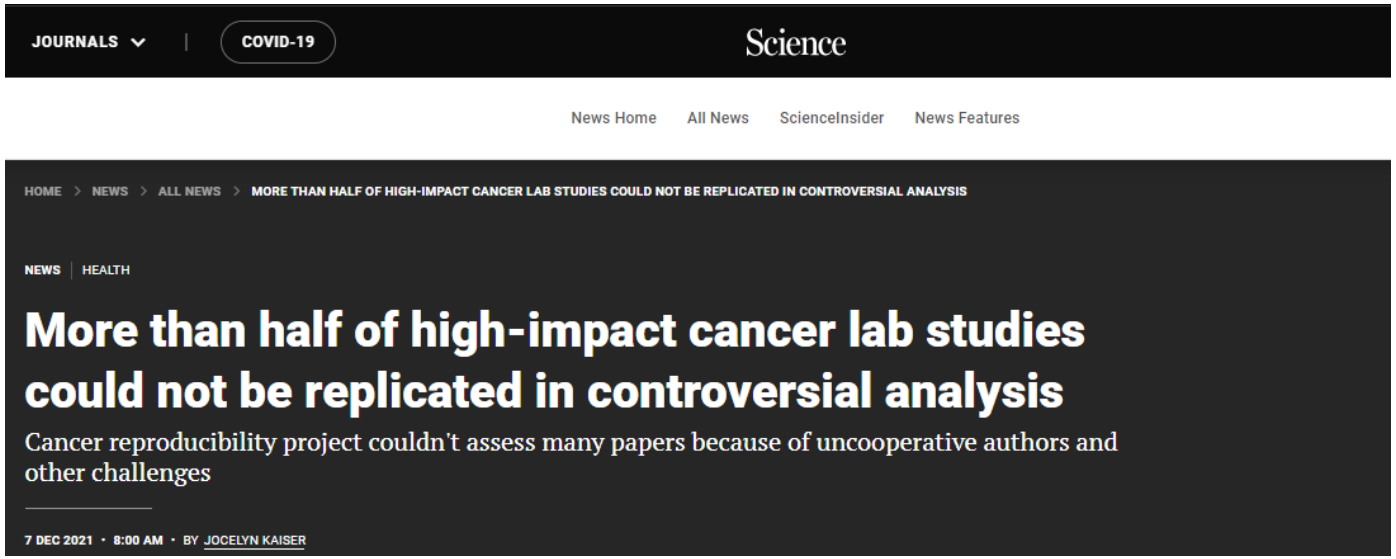
Trustworthiness of research hinges on reproducibility – how are we generally doing?



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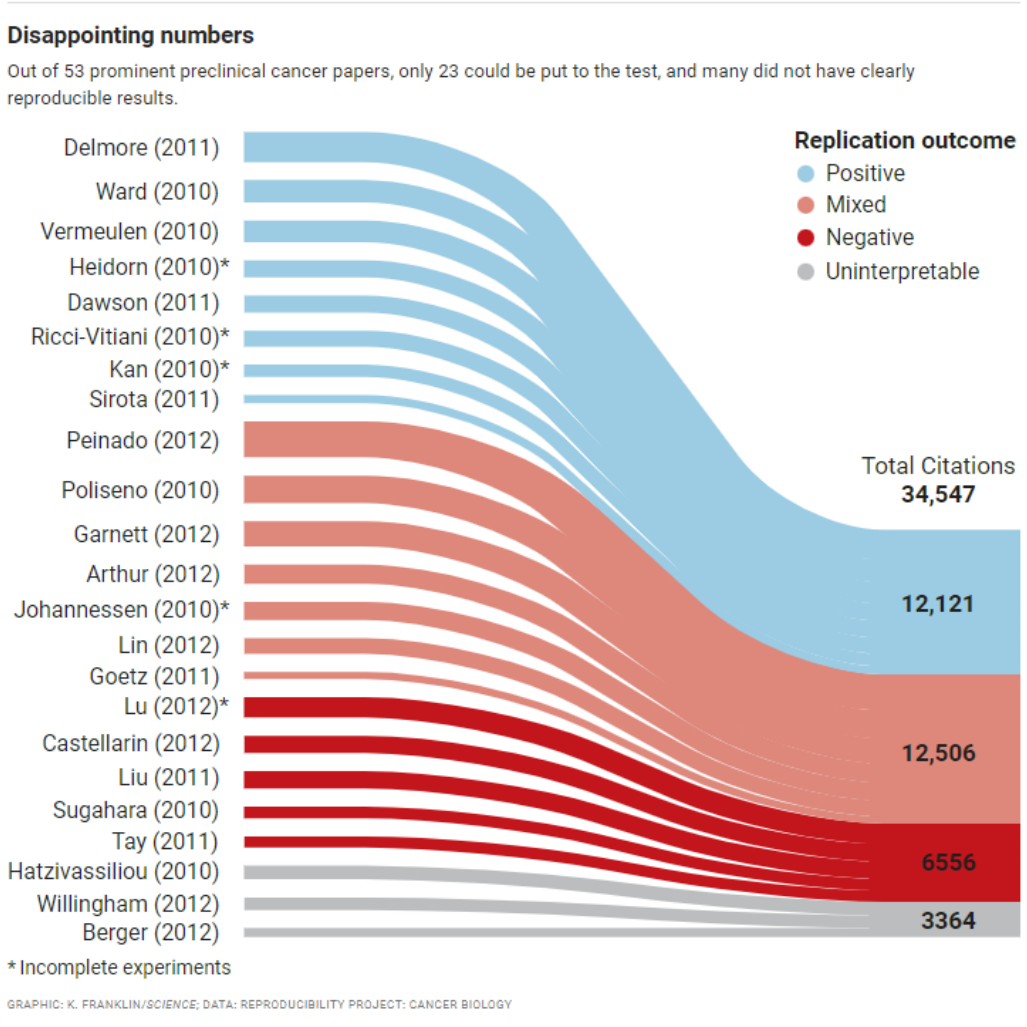
HOME > NEWS > ALL NEWS > MORE THAN HALF OF HIGH-IMPACT CANCER LAB STUDIES COULD NOT BE REPLICATED IN CONTROVERSIAL ANALYSIS

NEWS | HEALTH

More than half of high-impact cancer lab studies could not be replicated in controversial analysis

Cancer reproducibility project couldn't assess many papers because of uncooperative authors and other challenges

7 DEC 2021 • 8:00 AM • BY JOCELYN KAISER



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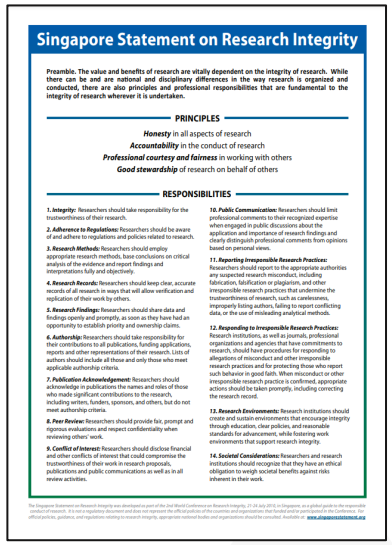
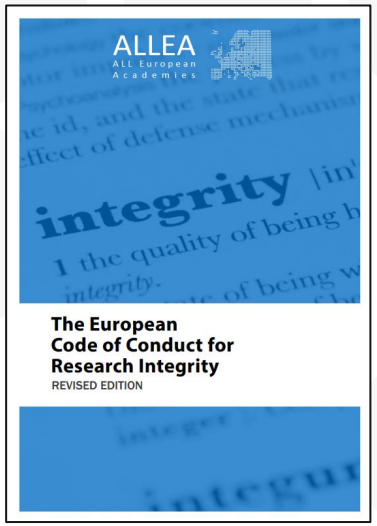
Codes of conduct aim to promote research integrity

Singapore Statement on Research Integrity, drafted at the Second World Conference on Research Integrity



The European Code of Conduct for Research Integrity – by ALLEA, the European Federation of Academies of Sciences and Humanities



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RAPTOR

Codes of conduct exist at multiple levels

Singapore Statement on Research Integrity, drafted at the Second World Conference on Research Integrity

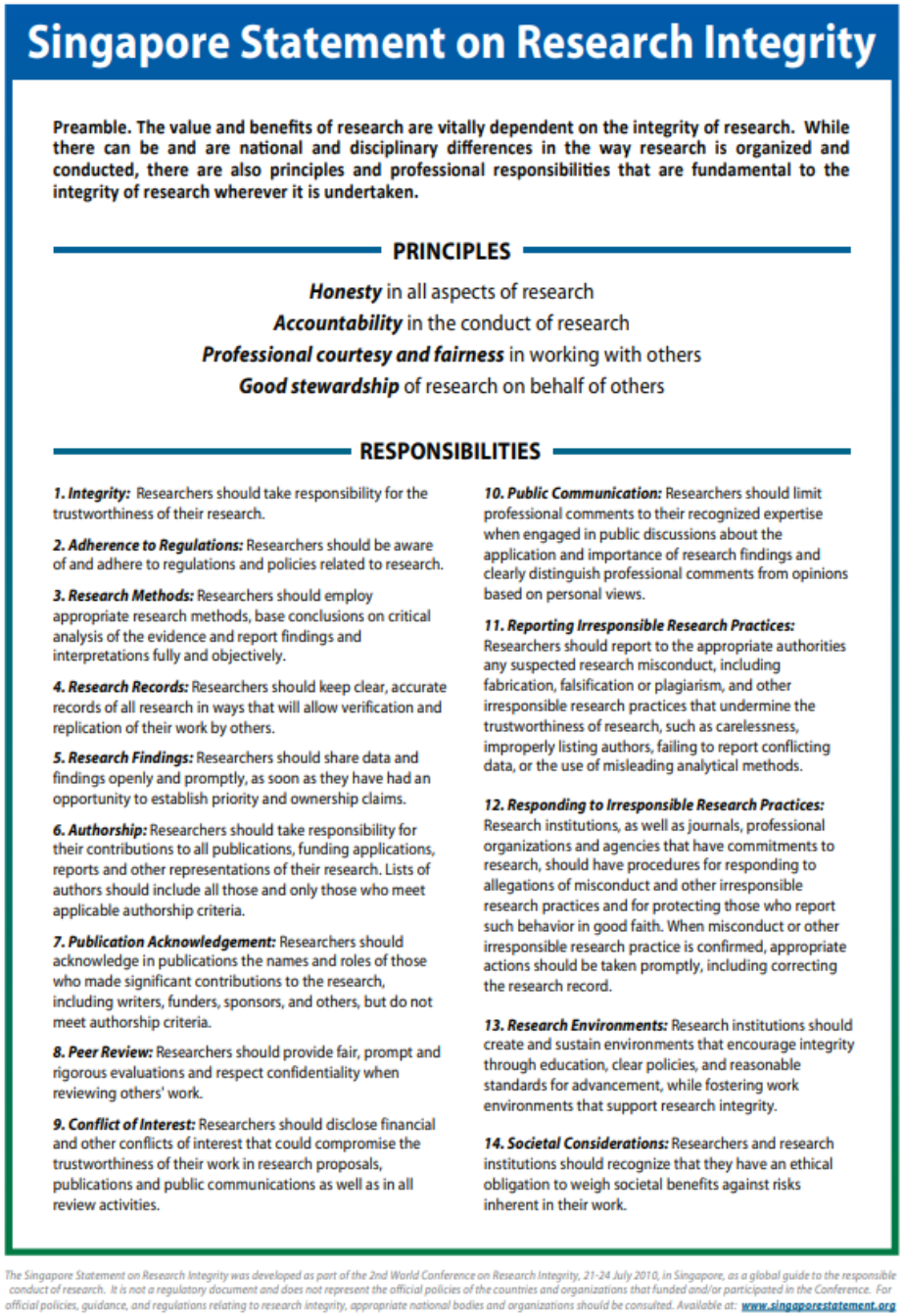
The European Code of Conduct for Research Integrity – by ALLEA, the European Federation of Academies of Sciences and Humanities

Danish Code of Conduct for Research Integrity – by Ministry of Higher Education and Science

Policy for research integrity, freedom of research and responsible conduct of research at Aarhus University

AARHUS UNIVERSITY

DCPT



Singapore Statement on Research Integrity

Preamble. The value and benefits of research are vitally dependent on the integrity of research. While there can be and are national and disciplinary differences in the way research is organized and conducted, there are also principles and professional responsibilities that are fundamental to the integrity of research wherever it is undertaken.

PRINCIPLES

Honesty in all aspects of research
Accountability in the conduct of research
Professional courtesy and fairness in working with others
Good stewardship of research on behalf of others

RESPONSIBILITIES

1. Integrity: Researchers should take responsibility for the trustworthiness of their research.

2. Adherence to Regulations: Researchers should be aware of and adhere to regulations and policies related to research.

3. Research Methods: Researchers should employ appropriate research methods, base conclusions on critical analysis of the evidence and report findings and interpretations fully and objectively.

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The global level: The Singapore Statement on Research Integrity

The objective of the Singapore statement is to promote global research integrity:

"… social, political, cultural, and economic differences among nations … affect the conduct of research and influence ethical norms …"

" … the Singapore Statement acknowledges these differences, but maintains that there are some common standards for research ethics that transcend national boundaries"

" … the intent of the Singapore Statement is to provide ethical guidance which research organizations, governments, and scientists can use to develop policies, regulations, and codes of conduct"

RAPTOR

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Four principles and fourteen responsibilities

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RAPTOR

The European level: Basic Principles of Research Integrity

Reliability

Ensuring quality of research in design, methodology, analysis and use of resources

Honesty

Transparent, fair, full, and unbiased developing, undertaking, reviewing, reporting and communicating of research

Respect

For colleagues, research participants, society, ecosystems, cultural heritage and the environment

Accountability

Management and organisation, training, supervision and mentoring, and wider impacts of research from idea to publication

Contexts of application of principles

- Research environment and culture
- Research procedures
- Supervision, training and mentoring
- Data management
- Collaboration
- Publication and dissemination
- Reviewing and editing

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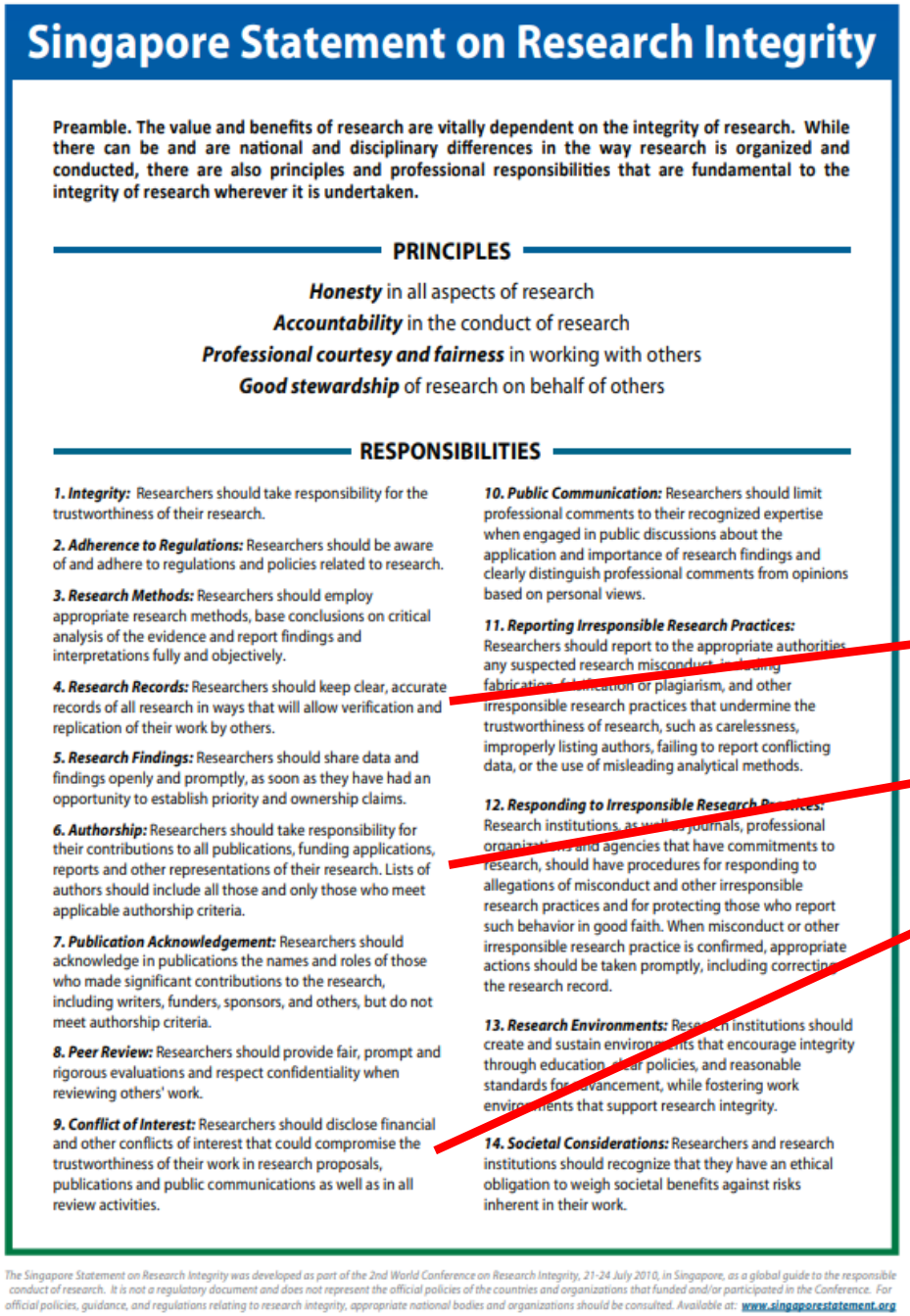

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5. Research Findings: Researchers should share data and findings openly and promptly, as soon as they have had an opportunity to establish priority and ownership claims.

6. Authorship: Researchers should take responsibility for their contributions to all publications, funding applications, reports and other representations of their research. Lists of authors should include all those and only those who meet applicable authorship criteria.

7. Publication Acknowledgement: Researchers should acknowledge in publications the names and roles of those who made significant contributions to the research, including writers, funders, sponsors, and others, but do not meet authorship criteria.

8. Peer Review: Researchers should provide fair, prompt and rigorous evaluations and respect confidentiality when reviewing others' work.

9. Conflict of Interest: Researchers should disclose financial and other conflicts of interest that could compromise the trustworthiness of their work in research proposals, publications and public communications as well as in all review activities.

10. Public Communication: Researchers should limit professional comments to their recognized expertise when engaged in public discussions about the application and importance of research findings and clearly distinguish professional comments from opinions based on personal views.

11. Reporting Irresponsible Research Practices: Researchers should report to the appropriate authorities any suspected research misconduct, including fabrication, falsification or plagiarism, and other irresponsible research practices that undermine the trustworthiness of research, such as carelessness, improperly listing authors, failing to report conflicting data, or the use of misleading analytical methods.

12. Responding to Irresponsible Research Practices: Research institutions, as well as journals, professional organizations and agencies that have commitments to research, should have procedures for responding to allegations of misconduct and other irresponsible research practices and for protecting those who report such behavior in good faith. When misconduct or other irresponsible research practice is confirmed, appropriate actions should be taken promptly, including correcting the research record.

13. Research Environments: Research institutions should create and sustain environments that encourage integrity through education, clear policies, and reasonable standards for advancement, while fostering work environments that support research integrity.

14. Societal Considerations: Researchers and research institutions should recognize that they have an ethical obligation to weigh societal benefits against risks inherent in their work.

The Singapore Statement on Research Integrity was developed as part of the 2nd World Conference on Research Integrity, 21-24 July 2010, in Singapore, as a global guide to the responsible conduct of research. It is not a regulatory document and does not represent the official policies of the countries and organizations that funded and/or participated in the Conference. For official policies, guidance, and regulations relating to research integrity, appropriate national bodies and organizations should be consulted. Available at: www.singaporestatement.org

Responsibilities are phrased to be operational

Examples:

Research records: Keep a logbook of your research

Authorship: Adhere to authorship criteria – include all authors who meet criteria

Conflict of interest: Disclose fully all potential conflicts, in all communications

What constitutes major misconduct?

- **Fabrication**

  “making up results and recording them as if they were real”

- **Falsification**

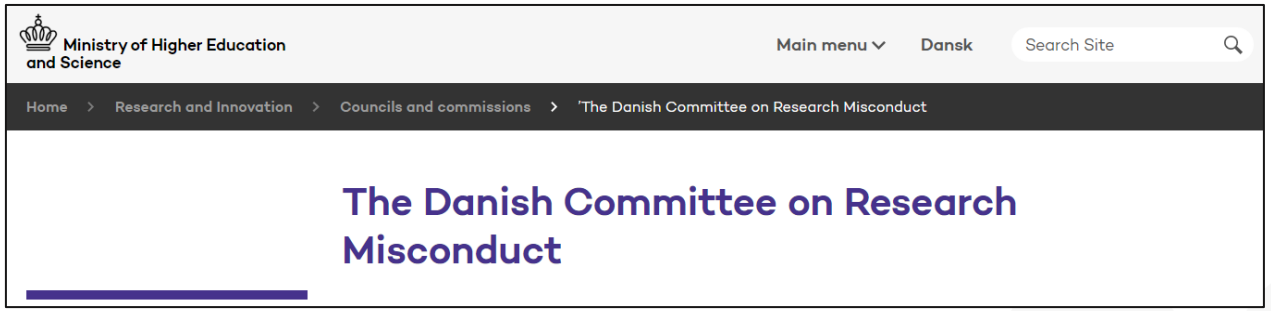
  “manipulating research materials, equipment or processes or changing, omitting or suppressing data or results without justification”

- **Plagiarism**

  “using other people’s work and ideas without giving proper credit to the original source”

How frequent is major misconduct?

In Denmark, scientific misconduct is regulated by law, and handled by the Danish Committee on Research Misconduct.



In 2020, decisions were made in 15 cases – scientific misconduct was found in 7 cases.

In 2019, decisions were made in 13 cases – scientific misconduct was found in 2 cases.

Of these 9 cases, plagiarism was the most common cause – six of them were plagiarism in PhD dissertations.

Questionable research practices

- Manipulating **authorship** or denigrating the role of other researchers in publications.
- Re-publishing substantive parts of one's own earlier publications, including translations, without duly acknowledging or citing the original ('**self-plagiarism**').
- **Citing selectively** to enhance own findings or to please editors, reviewers or colleagues.
- **Withholding research** results.
- Allowing funders/sponsors to **jeopardise independence** in the research process or reporting of results so as to introduce or promulgate bias.
- **Expanding unnecessarily** the bibliography of a study.
- **Accusing** a researcher of misconduct or other violations in a malicious way.
- **Misrepresenting** research achievements.
- **Exaggerating** the importance and practical applicability of findings.
- **Delaying** or inappropriately **hampering** the work of other researchers.
- **Misusing seniority** to encourage violations of research integrity.
- **Ignoring putative violations** of research integrity by others or covering up inappropriate responses to misconduct or other violations by institutions.
- Establishing or supporting journals that undermine the quality control of research ('**predatory journals**').

Problems from daily life – data

You do several measurement series to verify a new model developed in your group. One of the measurement series does not give the results you expect, and you discuss with the group how to proceed. You do not have material to repeat the measurement. Several explanations for error in the experiment setup are suggested, and the lab head ends up stating that most likely one part of the equipment gave an erroneous readout.

You have to decide whether to throw out the measurements, or to report them as part of your results.

Problems from daily life – exaggeration

You have been given the opportunity to present your results at a high-profile scientific conference. When the conference approaches, parts of your analysis do not demonstrate significance towards your expected result. Based on the parts that do demonstrate significance and the overall trend of the analysis, you all have a clear feeling that your expected result will hold up once more data is added.

You have to decide whether to present the non-significant results explicitly, or to focus more qualitatively on the overall trends.

Problems from daily life – authorship

You are writing a manuscript as first author, on a study which was performed in collaboration with a company which manufactures equipment used in your research. The company representative who was involved in the study has contributed to reading and editing the manuscript, and indeed did end up phrasing parts of the text, but states that she does not want to be coauthor – it is fine that you just mention her in the acknowledgments.

You have to decide whether to include her in the author list or not.

Break-out group discussions

- You will be divided in groups of 6-7 participants, and moved to break-out rooms
- You will have 10 minutes for discussion in the groups

- **The groups will be presented with two separate dilemmas for discussion, concerning authorship and data analysis**
- **Along with each dilemma, you will be given different options for responses/reactions**
  - **there is not one correct answer, rather you may use the options to discuss the pro's and con's**
  - **feel free to also give your own alternative response options**
- **Take approximately 5 minutes to discuss each dilemma**
- **For each dilemma, note down one short key consideration/reflection you find to be important**
- **After the break-out, we will share reflections using www.menti.com, code 8450 8286**

Dilemma 1:

You are writing a manuscript as first author and are approached by a senior author who asks you to include an external colleague on the author list. The external colleague has been peripherally involved in discussion of some of the ideas in the paper but has not participated directly. However, the senior author argues that there is a general good collaboration and that the goodwill of the external colleague may be useful in the future.

Options:

1. You follow the suggestion of the more senior author.
2. You send the manuscript to the suggested new co-author, and ask for input for both analysis, results and text.
3. You ask another independent colleague for advice, which you then follow.
4. You decline and report the senior author to the department head.

Dilemma 2:

You are writing a manuscript which is a continuation of previous work which has already been published by you. During data analysis for this new publication, you discover an error in your previous data analysis. The senior author of the first paper does not find the error to be of high importance, as it does not change the conclusion and was not noticed in previous peer review.

Options:

1. You just continue the new manuscript, using the corrected analysis.
2. You use the corrected analysis in the new paper and incorporate an explicit mention of the error into the text.
3. You write an independent erratum to your first paper and insist that it be submitted.
4. You send the question to all co-authors of both papers and go with the majority vote.

Break-out group discussion follow-up

Go to **www.menti.com** and use the code **8450 8286**

Write one short key consideration for dilemma 1 - authorship

VOTE

option 2	Option 2	Option 2
We would go for option two, interpreting the seniors advice benevolently and reading into it a suggestion of collaboration right now, instead of a "favor". On the other hand the person might've contributed considerably enough, we couldn't be sure.	Option 2 sounds reasonable, but it postpones the issue: if they give valuable input you can include them, but if not, what do you do? We also found that most of us have been involved into a similar situation, and reflect on it in personal way	Include the person in the acknowledgment part

Break-out group discussion follow-up

Go to **www.menti.com** and use the code **8450 8286**

Write one short key consideration for dilemma 2 - data analysis

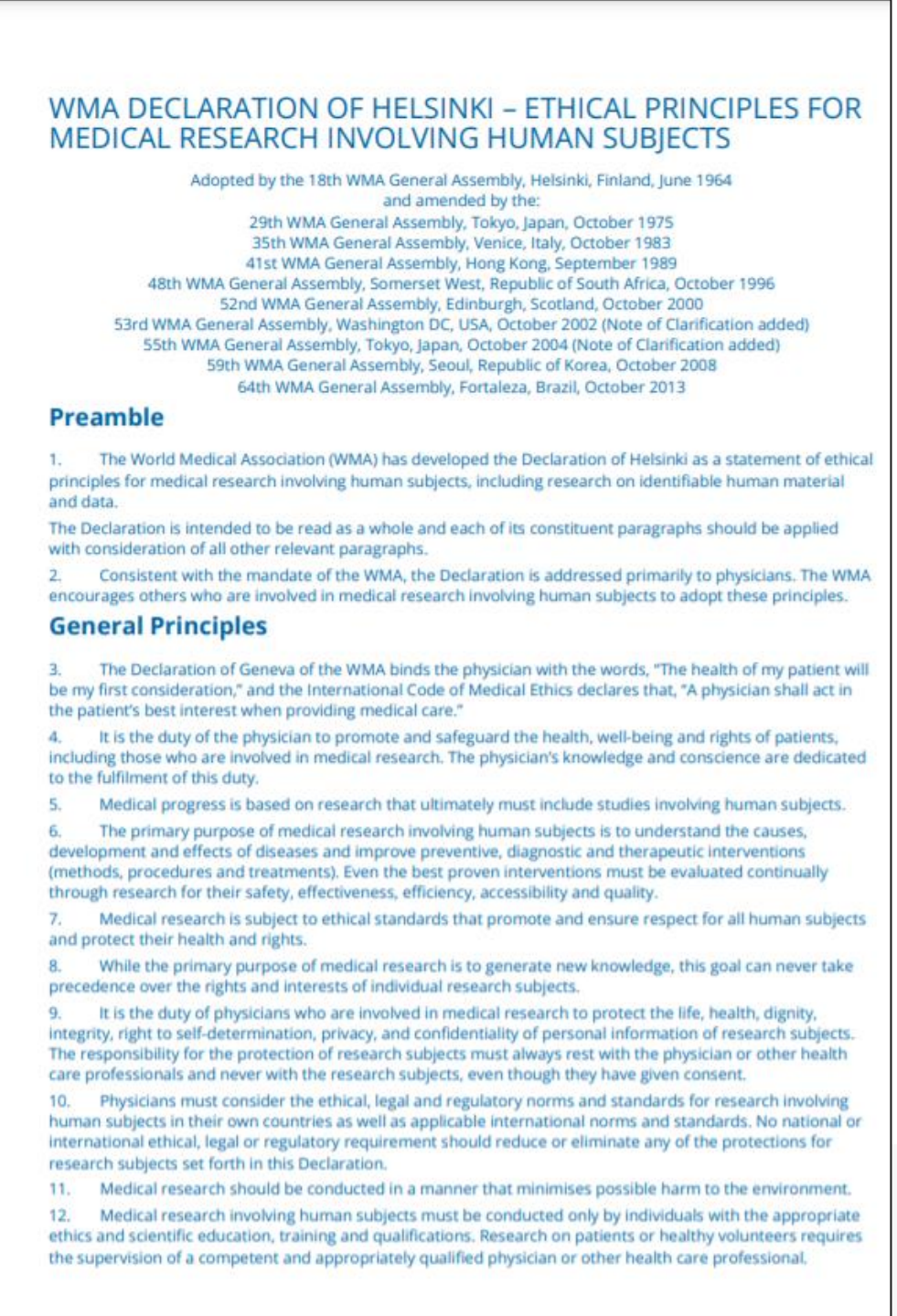
VOTE

Option 2 and 3 combined

Option 2

The crux here is the 'severity' of the error. Depending on how much you disagree with your senior you might go with option two or three too. Noone thought just correcting it without mention was okay.

Honesty about previous error seemed important to everybody. We would fix the error in the new work and explicitly state that we did something wrong. The key point is that the senoir scientist judges that the error is small



WMA DECLARATION OF HELSINKI – ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964
and amended by the:
29th WMA General Assembly, Tokyo, Japan, October 1975
35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September 1989
48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
52nd WMA General Assembly, Edinburgh, Scotland, October 2000
53rd WMA General Assembly, Washington DC, USA, October 2002 (Note of Clarification added)
55th WMA General Assembly, Tokyo, Japan, October 2004 (Note of Clarification added)
59th WMA General Assembly, Seoul, Republic of Korea, October 2008
64th WMA General Assembly, Fortaleza, Brazil, October 2013

Preamble

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.

The Declaration is intended to be read as a whole and each of its constituent paragraphs should be applied with consideration of all other relevant paragraphs.

2. Consistent with the mandate of the WMA, the Declaration is addressed primarily to physicians. The WMA encourages others who are involved in medical research involving human subjects to adopt these principles.

General Principles

3. The Declaration of Geneva of the WMA binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act in the patient's best interest when providing medical care."

4. It is the duty of the physician to promote and safeguard the health, well-being and rights of patients, including those who are involved in medical research. The physician's knowledge and conscience are dedicated to the fulfilment of this duty.

5. Medical progress is based on research that ultimately must include studies involving human subjects.

6. The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best proven interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.

7. Medical research is subject to ethical standards that promote and ensure respect for all human subjects and protect their health and rights.

8. While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.

9. It is the duty of physicians who are involved in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects. The responsibility for the protection of research subjects must always rest with the physician or other health care professionals and never with the research subjects, even though they have given consent.

10. Physicians must consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.

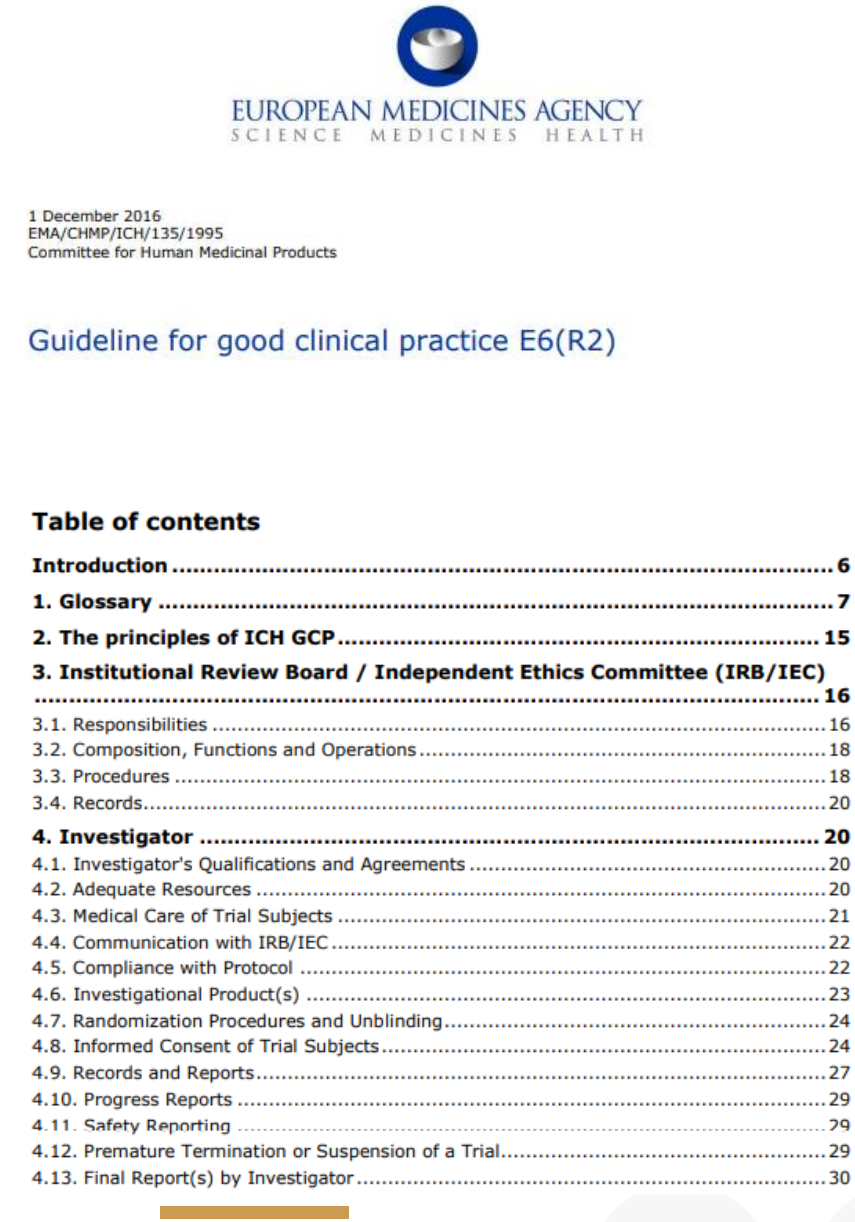
11. Medical research should be conducted in a manner that minimises possible harm to the environment.

12. Medical research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional.

Working with human subjects requires special considerations

The World Medical Association Declaration of Helsinki sets guiding principles for ethical standards, including e.g.:

- Protecting Patient Health - Declaration of Geneva emphasizes “the health of my patient will be my first consideration”
- Knowledge Cannot Trample Rights - “This goal can never take precedence over the rights and interests of individual research subjects”
- “Medical research involving human subjects may only be conducted if the importance of the objective outweighs the risks and burdens to the research subjects.”
- “Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary.”



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 December 2016
EMA/CHMP/ICH/135/1995
Committee for Human Medicinal Products

Guideline for good clinical practice E6(R2)

Table of contents

European level – European Medicines Agency

"Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki …"

The guidelines describe

- Principles of good clinical practice
- Roles of responsibilities of involved entities;
  - Institutional review board
  - Investigator
  - Sponsor
- Requirements for clinical trial protocols

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Essential documents to know

- Singapore Statement on Research Integrity, drafted at the Second World Conference on Research Integrity
- The European Code of Conduct for Research Integrity – by ALLEA, the European Federation of Academies of Sciences and Humanities
- Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals (also known as the Vancouver Convention) - by the International Committee of Medical Journal Editors (ICMJE)
- World Medical Association Declaration of Helsinki – Ethical Principles For Medical Research Involving Human Subjects

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Everybody makes mistakes

Mistakes should be handled in accordance with good scientific practice.

Errors in published data, analyses, results, conclusions, can be handled by publishing addenda/errata or ultimately by retracting.

"We show that human players are able to find solutions to difficult problems associated with the task of quantum computing[6]. Players succeed where purely numerical optimization fails, and analyses of their solutions provide insights into the problem of optimization of a more profound and general nature."

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During this time, the results were contested and questioned by several independent scientists. Delay in sharing code was severely critizised.

"The authors have alerted the editors of Nature to an error in the code underlying the work in this Letter, and have informed us that this error will have an impact on the conclusions that can reliably be drawn. Nature is working with the authors to resolve the matter, but in the meantime, readers are cautioned against using results from this Letter.

Everybody makes mistakes

Mistakes should be handled in accordance with good scientific practice.

Errors in published data, analyses, results, conclusions, can be handled by publishing addenda/errata or ultimately by retracting.

During this time, the results were contested and questioned by several independent scientists. Delay in sharing code was severely critizised.

"We, the authors, are regretfully retracting this Article owing to an error in our computer code that means the quantitative results reported are not valid."

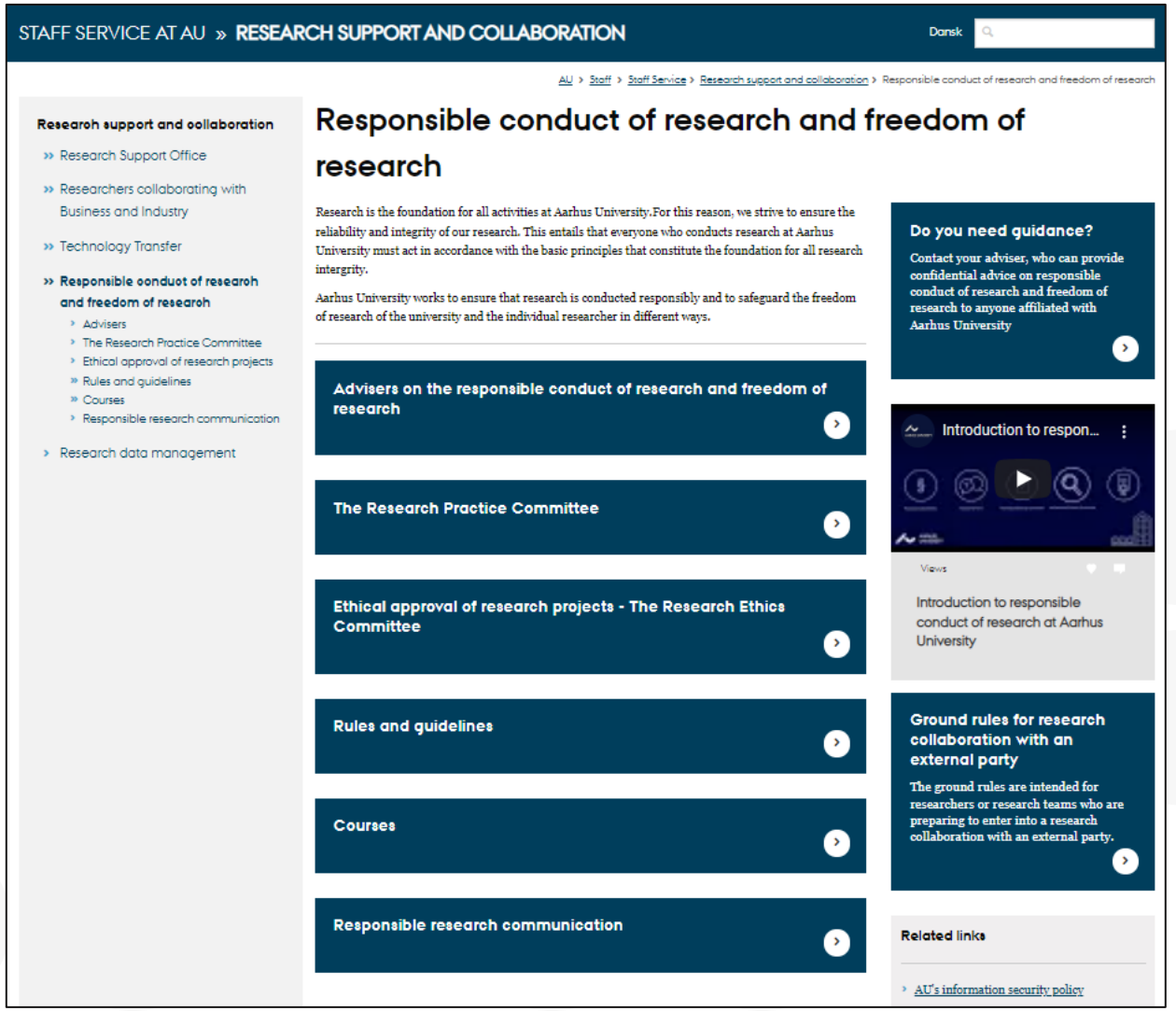
Everybody makes mistakes

It is not the mistake itself that is a problem – it is how you handle it!

When it doubt – consult your guidelines and ask your peers, your supervisor, your mentor, and/or an independent advisor.

Make yourself acquainted with resources available to you

Example Aarhus University:



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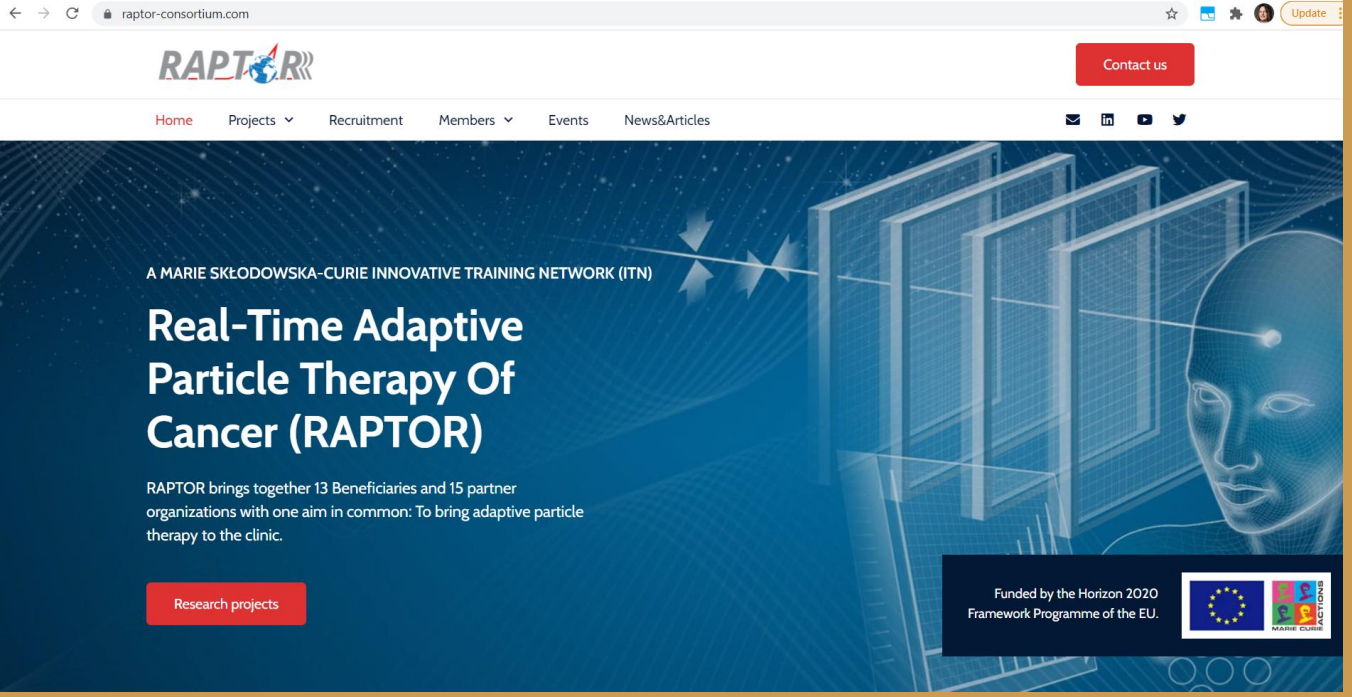

Use Menti to state your key message from this talk!

Go to **www.menti.com** and use the code **8450 8286**

State your key message from this talk in one word

VOTE

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