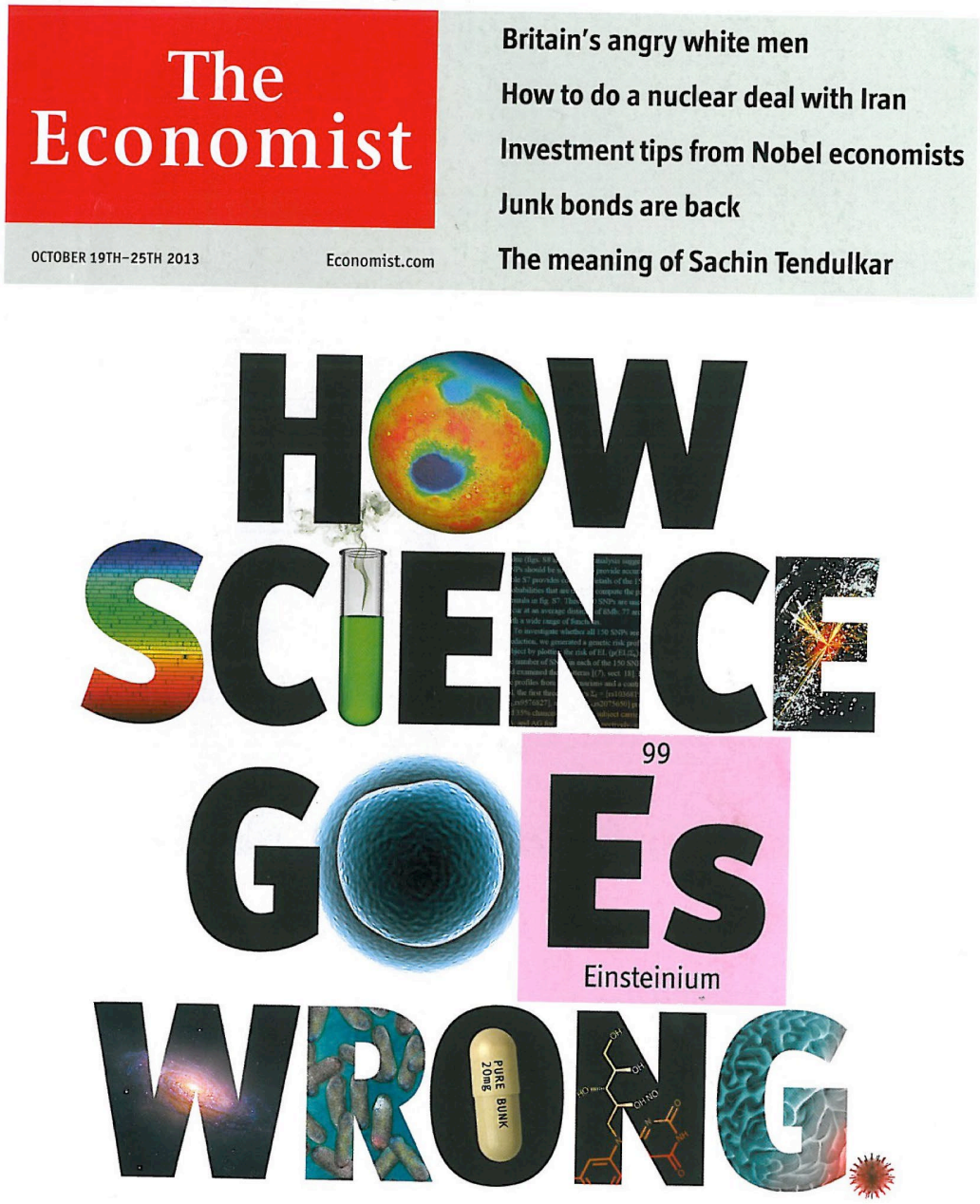
What is the role of journals and publishers in driving research standards?

Véronique Kiermer, PhD
Director, Author & Reviewer Services
Nature Publishing Group

WCRI 2015 | Rio de Janeiro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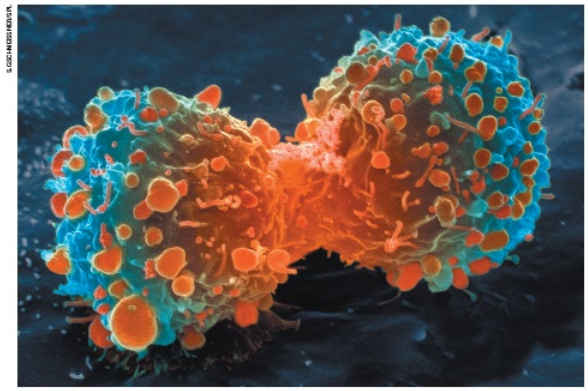
Essay

Why Most Published Research Findings Are False

John P. A. Ioannidis

PloS Medicine 2005
doi: 10.1371/journal.pmed.0020124



Many landmark findings in preclinical oncology research are not reproducible, in part because of inadequate cell lines and animal models.

Raise standards for preclinical cancer research

C. Glenn Begley and Lee M. Ellis propose how methods, publications and incentives must change if patients are to benefit.

Nature 2012
doi:10.1038/483531a

NRDD 2011
doi: doi:10.1038/nrd3439-c1

Believe it or not: how much can we rely on published data on potential drug targets?

Florian Prinz, Thomas Schlange and Khusru Asadullah

What We Talk About When We Talk About Reproducibility

- ✓ We are not talking about fraud.

- ✓ We are not talking about fraud.
- ✓ We acknowledge that reasonable conclusions derived from legitimate observations can be disproved by subsequent knowledge and technology advancements.

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- ✓ We acknowledge that reasonable conclusions derived from legitimate observations can be disproved by subsequent knowledge and technology advancements.
- ✓ We distinguish: replication ≠ generalization

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- ✓ We distinguish: replication ≠ generalization
  …and we draw conclusions accordingly.

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- ✓ We acknowledge that reasonable conclusions derived from legitimate observations can be disproved by subsequent knowledge and technology advancements.
- ✓ We distinguish: replication ≠ generalization
  …and we draw conclusions accordingly.
- ✓ We must talk about and reduce irreproducibility due to cherry picking, uncontrolled experimenter bias, poor experimental design, statistical insignificance, over-fitting of models to noisy data, faulty reagents, inappropriate data presentation, …

What can journals do?

Raise awareness

- Tackling the widespread and critical impact of batch effects in high-throughput data, Leek *et al*., *NRG*, Oct 2010
- How much can we rely on published data on potential drug targets? Prinz et al., *NRDD*, Sep 2011
- The case for open computer programs, Ince *et al.*, *Nature*, Feb 2012
- Raise standards for preclinical cancer research, Begley & Ellis, *Nature,* Mar 2012
- Must try harder – Editorial, *Nature*, Mar 2012
- Face up to false positives, MacArthur, *Nature*, Jul 2012
- Error prone – Editorial, *Nature*, Jul 2012
- Next-generation sequencing data interpretation: enhancing reproducibility and accessibility, Nekrutenko & Taylor, *NRG*, Sep 2012
- A call for transparent reporting to optimize the predictive value of preclinical research. Landis *et al.*, *Nature*, Oct 2012
- Know when your numbers are significant, Vaux, *Nature*, Dec 2012
- Reuse of public genome-wide gene expression data, Rung & Brazma, *NRG*, Feb 2013
- Reducing our irreproducibility – Editorial, *Nature*, May 2013
- Reproducibility: Six red flags for suspect work, Begley, *Nature*, May 2013
- Reproducibility: The risks of the replication drive, Bissell, *Nature*, Nov 2013

http://www.nature.com/nature/focus/reproducibility/index.html

Participate in community debates

NINDS meeting June 2012
NCI meeting September 2012

PERSPECTIVE

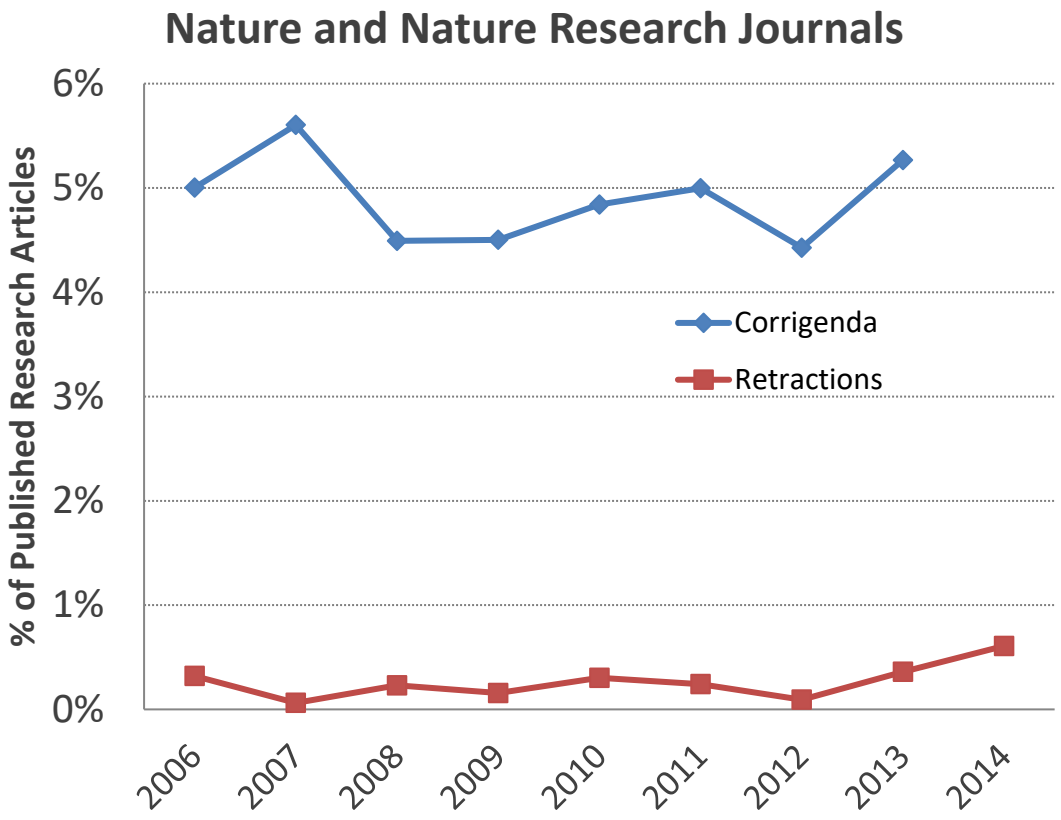
doi:10.1038/nature11556

A call for transparent reporting to optimize the predictive value of preclinical research

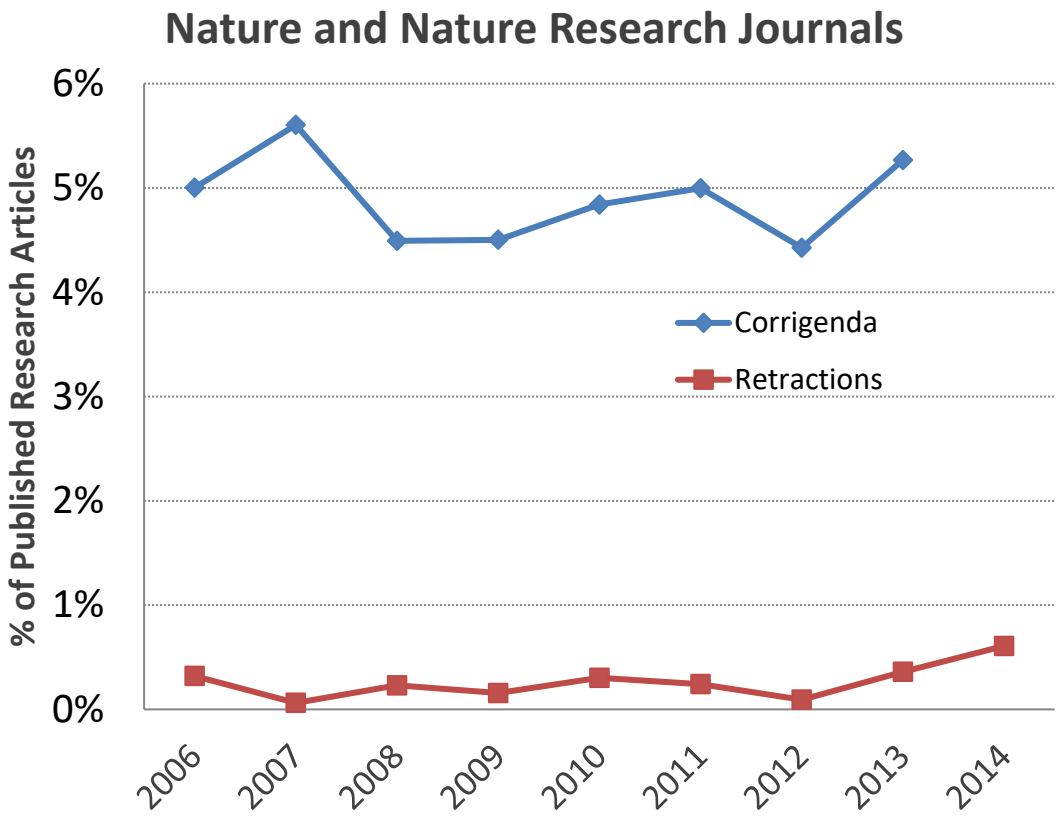
Story C. Landis[1], Susan G. Amara[2], Khusru Asadullah[3], Chris P. Austin[4], Robi Blumenstein[5], Eileen W. Bradley[6], Ronald G. Crystal[7], Robert B. Darnell[8], Robert J. Ferrante[9], Howard Fillit[10], Robert Finkelstein[1], Marc Fisher[11], Howard E. Gendelman[12], Robert M. Golub[13], John L. Goudreau[14], Robert A. Gross[15], Amelie K. Gubitz[1], Sharon E. Hesterlee[16], David W. Howells[17], John Huguenard[18], Katrina Kelner[19], Walter Koroshetz[1], Dimitri Krainc[20], Stanley E. Lazic[21], Michael S. Levine[22], Malcolm R. Macleod[23], John M. McCall[24], Richard T. Moxley III[25], Kalyani Narasimhan[26], Linda J. Noble[27], Steve Perrin[28], John D. Porter[1], Oswald Steward[29], Ellis Unger[30], Ursula Utz[1] & Shai D. Silberberg[1]

The US National Institute of Neurological Disorders and Stroke convened major stakeholders in June 2012 to discuss how to improve the methodological reporting of animal studies in grant applications and publications. The main workshop recommendation is that at a minimum studies should report on sample-size estimation, whether and how animals were randomized, whether investigators were blind to the treatment, and the handling of data. We recognize that achieving a meaningful improvement in the quality of reporting will require a concerted effort by investigators, reviewers, funding agencies and journal editors. Requiring better reporting of animal studies will raise awareness of the importance of rigorous study design to accelerate scientific progress.

Introspection: formal corrections



Introspection: formal corrections



- Missing controls
- Results not sufficiently representative of experimental variability
- Data selection
- Investigator bias
- Technical replicates wrongly described as biological replicates
- Contamination of primary culture cells
- Over-fitting of models for noisy datasets, e.g., fMRI, x-ray crystallography, machine learning
- Errors and inappropriate manipulation in image presentation
- Poor data management

Underlying issues

- experimental design
- statistics literacy
- data presentation

- data management
- reagents validity

- pressure to publish
- publication bias
- replications and refutations not pursued

REMEDIES
training laboratory management leadership & mentoring size of laboratories
infrastructure oversight and compliance quality assurance
incentives for rigor, professionalism and good laboratory leadership

Journals can take action

CONSORT guidelines

Reporting randomized clinical trials

OPEN ACCESS Freely available online

PLoS MEDICINE

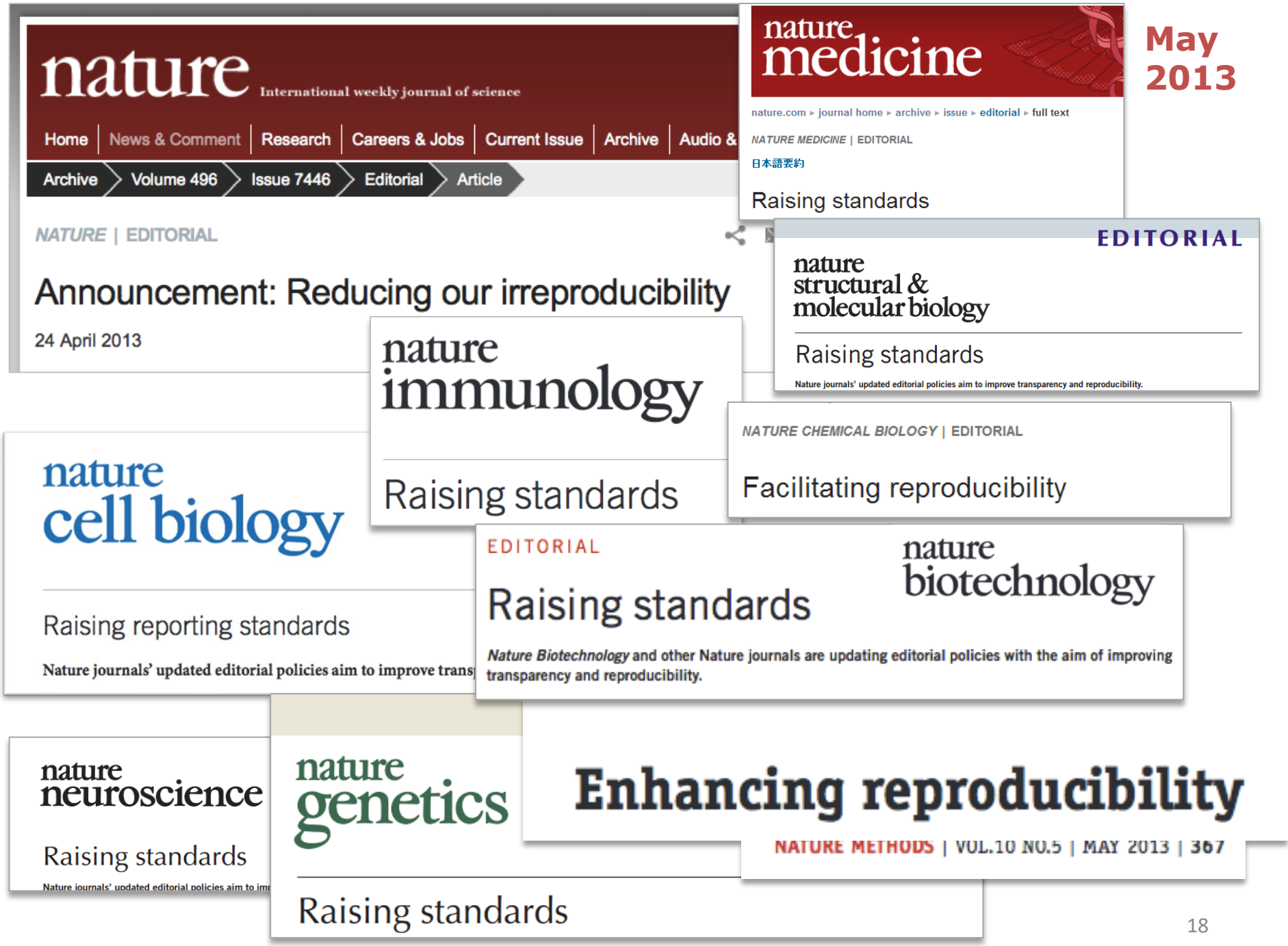
Guidelines and Guidance

CONSORT 2010 Statement: Updated Guidelines for Reporting Parallel Group Randomised Trials

Kenneth F. Schulz[1]*, Douglas G. Altman[2], David Moher[3], for the CONSORT Group[¶]

1 Family Health International, Research Triangle Park, North Carolina, United States of America, **2** Centre for Statistics in Medicine, University of Oxford, Wolfson College, Oxford, United Kingdom, **3** Ottawa Methods Centre, Clinical Epidemiology Program, Ottawa Hospital Research Institute, Department of Epidemiology and Community Medicine, University of Ottawa, Ottawa, Canada

equator network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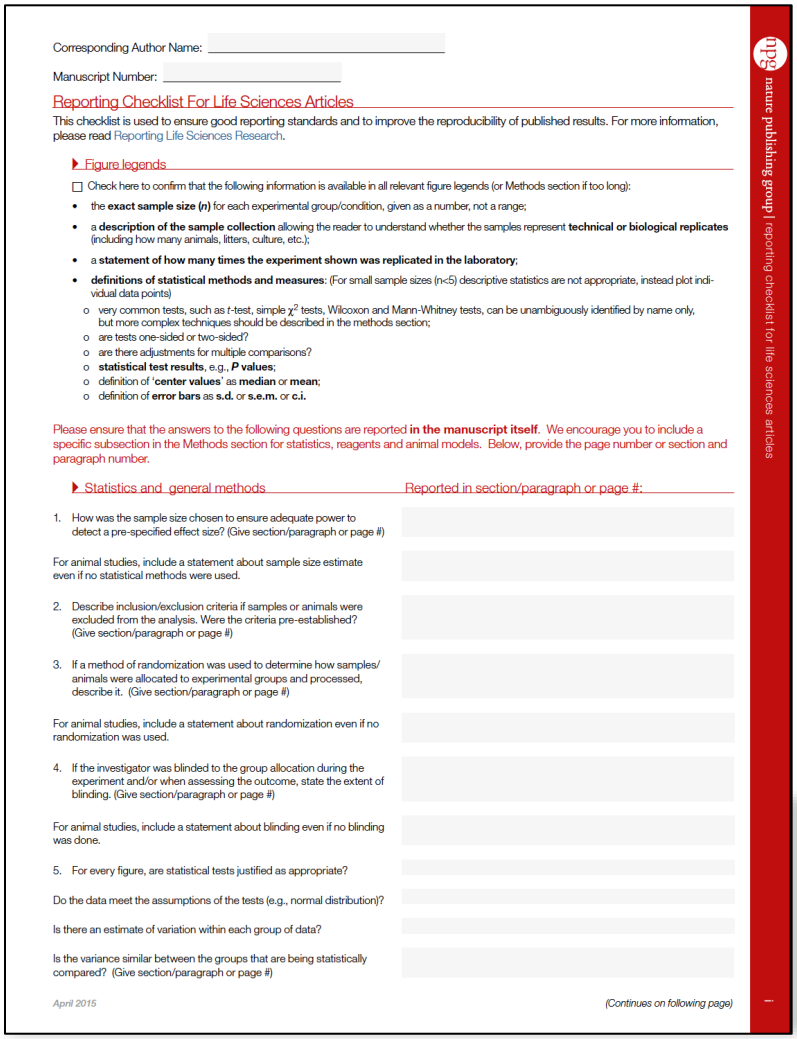
Enhancing reproducibility
NATURE METHODS | VOL.10 NO.5 | MAY 2013 | 367

Editorial measures at Nature

Introduced May 2013 – focus on reporting



Corresponding Author Name: _____

Manuscript Number: _____

Reporting Checklist For Life Sciences Articles

This checklist is used to ensure good reporting standards and to improve the reproducibility of published results. For more information, please read Reporting Life Sciences Research.

▸ Figure legends

☐ Check here to confirm that the following information is available in all relevant figure legends (or Methods section if too long):

- the **exact sample size (*n*)** for each experimental group/condition, given as a number, not a range;
- a **description of the sample collection** allowing the reader to understand whether the samples represent **technical or biological replicates** (including how many animals, litters, culture, etc.);
- a **statement of how many times the experiment shown was replicated in the laboratory**;
- **definitions of statistical methods and measures**: (For small sample sizes (n<5) descriptive statistics are not appropriate, instead plot individual data points)
  - very common tests, such as *t*-test, simple χ^2 tests, Wilcoxon and Mann-Whitney tests, can be unambiguously identified by name only, but more complex techniques should be described in the methods section;
  - are tests one-sided or two-sided?
  - are there adjustments for multiple comparisons?
  - **statistical test results**, e.g., ***P* values**;
  - definition of '**center values**' as **median** or **mean**;
  - definition of **error bars** as **s.d.** or **s.e.m.** or **c.i.**

Please ensure that the answers to the following questions are reported **in the manuscript itself**. We encourage you to include a specific subsection in the Methods section for statistics, reagents and animal models. Below, provide the page number or section and paragraph number.

▸ Statistics and general methods — Reported in section/paragraph or page #:

1. How was the sample size chosen to ensure adequate power to detect a pre-specified effect size? (Give section/paragraph or page #)

For animal studies, include a statement about sample size estimate even if no statistical methods were used.

2. Describe inclusion/exclusion criteria if samples or animals were excluded from the analysis. Were the criteria pre-established? (Give section/paragraph or page #)

3. If a method of randomization was used to determine how samples/animals were allocated to experimental groups and processed, describe it. (Give section/paragraph or page #)

For animal studies, include a statement about randomization even if no randomization was used.

4. If the investigator was blinded to the group allocation during the experiment and/or when assessing the outcome, state the extent of blinding. (Give section/paragraph or page #)

For animal studies, include a statement about blinding even if no blinding was done.

5. For every figure, are statistical tests justified as appropriate?

Do the data meet the assumptions of the tests (e.g., normal distribution)?

Is there an estimate of variation within each group of data?

Is the variance similar between the groups that are being statistically compared? (Give section/paragraph or page #)

April 2015 (Continues on following page)

npg nature publishing group | reporting checklist for life sciences articles i

1. Checklist of reporting standards
2. Eliminated length limits for methods sections
   - up to 50% increase
3. Increased scrutiny of statistics
   - Statistical advisor: Terry Hyslop
   - pool of statistical consultants
4. Re-emphasized data sharing
   - stress use of repositories
   - data descriptors – Scientific Data
   - source data – aka 'data behind graphs'

nature.com/authors/checklist.pdf

Is it working?

Impact assessment

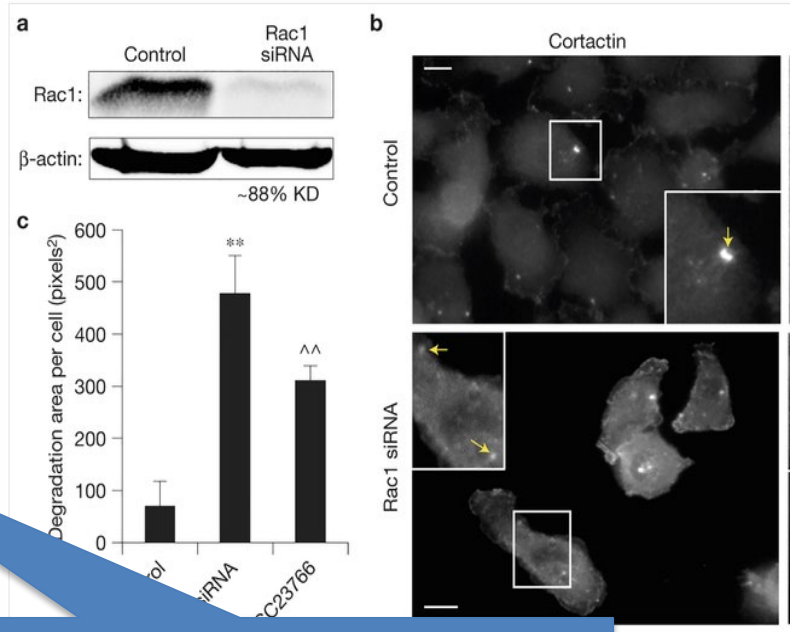
Under way

- Independent study commissioned: meta-analysis of published papers
- Malcolm Macleod (University of Edinburgh), Emily Sena (University of Edinburgh/ Florey Neurosciences Institute), David Howells (Florey Neurosciences Institute) – CAMARADES
- Funded by Arnold Foundation
- Focus on reporting quality and completeness

➔ Impact assessment to be published independently

➔ Actionable outcomes to guide further actions

(a) Western blot of cell lysates of control and Rac1-siRNA-treated MTLn3 cells, blotted for Rac1 and β-actin**. A representative image is shown from 3 blots**. (b) MTLn3 cells transfected with control or Rac1 siRNA and plated on Alexa-405-conjugated gelatin overnight. Arrows point to invadopodia and sites of degradation. Scale bars, 10 µm. Representative image sets are shown from 50 image sets each for the control and Rac1 siRNA. (c) Quantification of mean degradation area per cell from b, including Rac1 inhibitor NSC23766 treatment at 100 µM**. *n* = 60 fields for each condition, pooled from 5 independent experiments; error bars are s.e.m. Student's *t*-test was used.** $^{**}P = 0.00022$,^ ^$P = 0.011639$. **Uncropped images of blots** are shown in Supplem ntary Fig. 9.



statement of replication

definition of *n*

raw source data

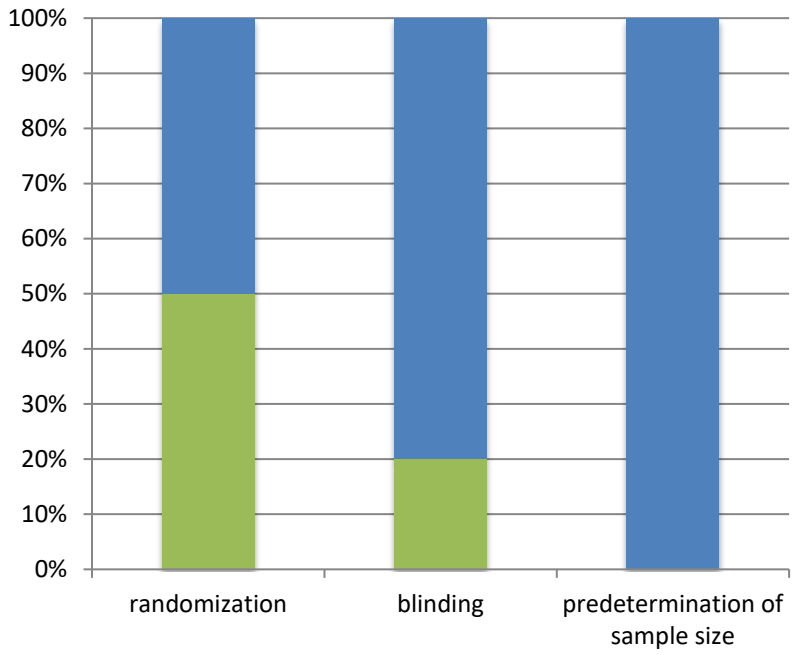
definition of statistic tests

Nature Cell Biology **16**, 571–583 (2014)
doi:10.1038/ncb2972

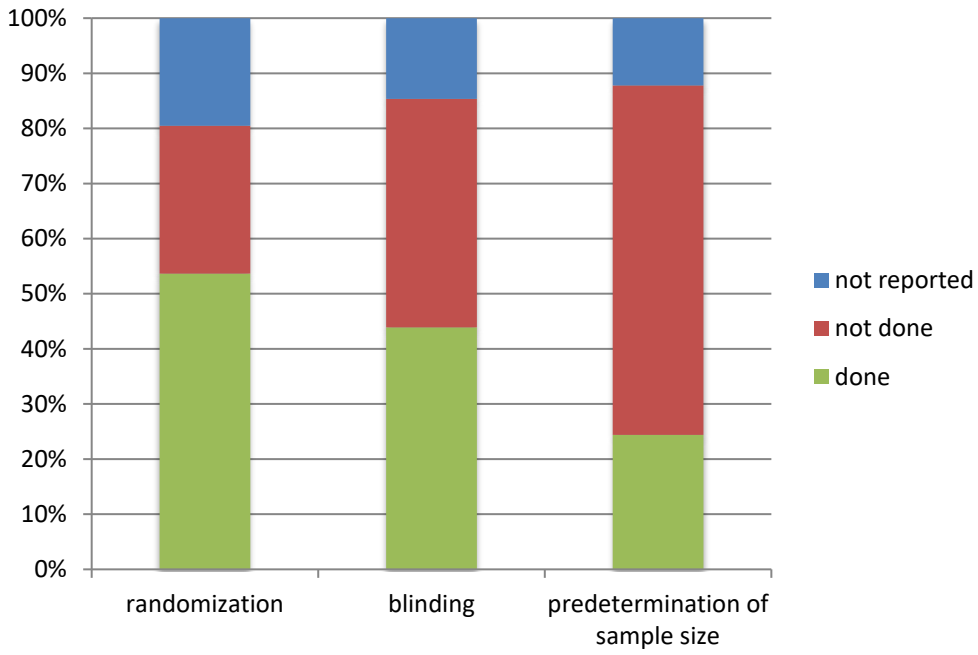
Reporting animal experiments

Nature Neuroscience

Jan ‘12 (10 papers)



Oct ‘13 – Jan ‘14 (41 papers)



“Not reported” includes cases for which the specific question was not relevant (e.g. investigator cannot be blinded to treatment)

An ongoing process…

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The NIH Director

Proposed Principles and Guidelines for Reporting Preclinical Research

The signatories represent journals that publish preclinical biological research — an area of research that encompasses both exploratory studies

Background

NIH held a joint workshop in June 2014 with the Nature Publishing Group and Science on the issue of reproducibility and rigor of research findings, with journal editors representing over 30 preclinical science journals in NIH-funded investigators have often published. The workshop ed on the common opportunities scientific publishing arena to ce rigor and further support

EDITORIAL

Journals unite for reproducibility

Reproducibility, rigor, transparency, and independent verification are cornerstones of the scientific method. Of course, just because a result is reproducible does not necessarily make it right, and just because it is not reproducible does not necessarily make it wrong. A transparent and rigorous approach, however, can almost always shine a light on issues of reproducibility. This light ensures that science moves forwardmenters were blind to the conduct of the experiment, how the sample size was determined, and what criteria were used to include or exclude any data. Journals should recommend the deposition of data in public repositories where available and link data bidirectionally to the published paper. Journals should strongly encourage, as appropriate, that all materials used in the experiment be shared with those who wish to replicate the experiment. Once a journal publishes a paper,

Science

AAAS

nature

Journals unite for reproducibility

Consensus on reporting principles aims to improve quality control in biomedical research and encourage public trust in science.

Reproducibility, rigour, transparency and independent verification are cornerstones of the scientific method. Of course, just because a result is reproducible does not make it right, and just because it is not reproducible does not make it wrong. A transparent and rigorous approach, however, will almost always shine a light on issues of

the sample size was determined and what criteria were used to include or exclude any data. Journals should recommend deposition of data in public repositories, where available, and link data bidirectionally when the paper is published. Journals should strongly encourage, as appropriate, that all materials used in the experiment be shared with those who

Nature journals policy on computer code

Code share

Papers in Nature journals should make computer code accessible where possible.

A theme in *Nature*'s ongoing campaign for the replicability and reproducibility of our research papers is that key components of publications should be available to peers who wish to validate the techniques and results.

A core element of many papers is the computer code used by authors in models, simulations and data analysis. In an ideal world, this code would always be transportable and easily used by others. In such a world, our editorial policy would be to insist on sharing to allow free use, as we already do (as far as is practicable) with data and research materials. Unfortunately, such an ideal is not easy to attain owing to the amount of extra funding and effort it would require to render some major pieces of code shareable. Nevertheless, we at *Nature* and the Nature research journals want to encourage as much sharing as possible.

Climate modellers have made some strides in this regard. The journal *Geoscientific Model Development* has a good example of such a policy (see go.nature.com/jv8g1w), and an article in *Nature Geoscience* discusses some of the opportunities presented by code sharing, as well as the obstacles (S. M. Easterbrook *Nature Geosci.* 7, 779–781; 2014).

As a leading example of transparency policies in other disciplines, the data journal *GigaScience* requires code used in its papers to be available, and hosts it in a way that allows others to analyse the data in publications. One point made by Easterbrook is that even if the code is shared, others might often make little or no use of it, but on some occasions the take-up will be large.

Nature and the Nature journals have decided that, given the diversity of practices in the disciplines we cover, we cannot insist on sharing computer code in all cases. But we can go further than we have in the past, by at least indicating when code is available. Accordingly, our policy now mandates that when code is central to reaching a paper's conclusions, we require a statement describing whether that code is available and setting out any restrictions on accessibility. Editors will insist on availability where they consider it appropriate: any practical issues preventing code sharing will be evaluated by the editors, who reserve the right to decline a paper if important code is unavailable. Moreover, we will provide a dedicated section in articles in which any information on computer code can be placed. And we will work with individual communities to put together best-practice guidelines and possibly more-detailed rules.

For full details, see our guide for authors at go.nature.com/o5ykhe. For an archive of our content and initiatives concerning reproducibility, see http://www.nature.com/nature/focus/reproducibility. ■

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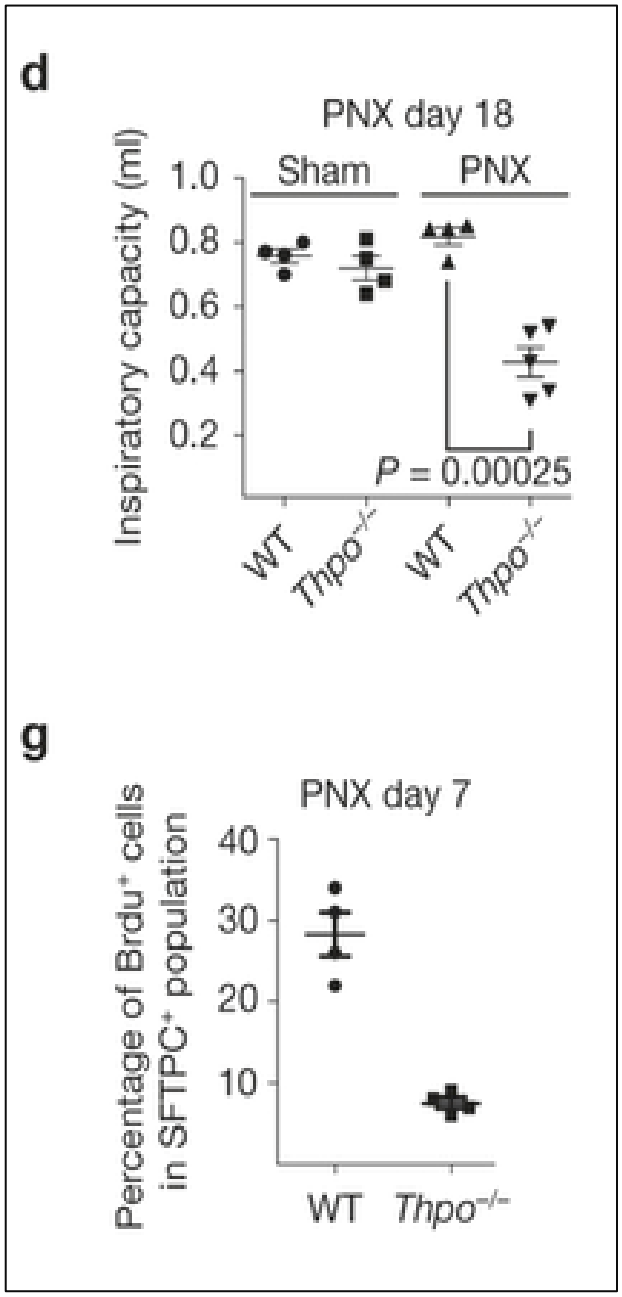
536 | NATURE | VOL 514 | 30 OCTOBER 2014



Nature Cell Biology **17**, 123–136 (2015) doi:10.1038/ncb3096

Data presentation

Kick the bar chart habit!

- We now recommend plotting individual data points for n<5
- *Nature Methods* worked with community to make a box plot tool available

BoxPlotR: a web tool for generation of box plots

To the Editor: In biomedical research, it is often necessary to compare multiple data sets with different distributions. The bar plot, or histogram, is typically used to compare data sets on the basis of simple statistical measures, usually the mean with s.d. or s.e.m. However, summary statistics alone may fail to convey underlying differences in the structure of the primary data (**Fig. 1a**), which may in turn lead to erroneous conclusions. The box plot, also

http://boxplot.tyerslab.com

Educational resources by Nature journals

Statistics for biologists and data visualization

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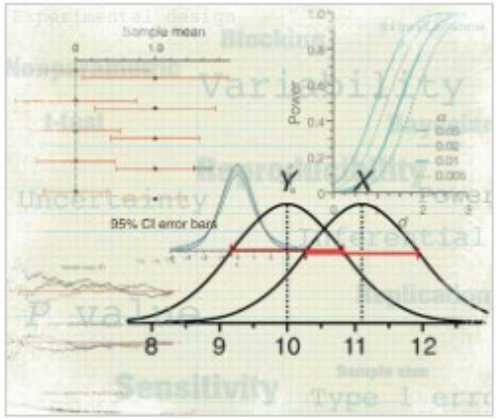


There is no disputing the importance of statistical analysis in biological research, but too often it is considered only after an experiment is completed, when it may be too late.

This collection highlights important statistical issues that biologists should be aware of and provides practical advice to help them improve the rigor of their work.

Nature Methods' **Points of Significance** column on statistics explains many key statistical and experimental design concepts. **Other resources** include an online plotting tool and links to statistics guides from other publishers.

Image Credit: Erin DeWalt

Statistics in biology

Nature News | Editorial

Number crunch

Nature | Comments and Opinion

Research methods: Know when your numbers are significant

David L. Vaux

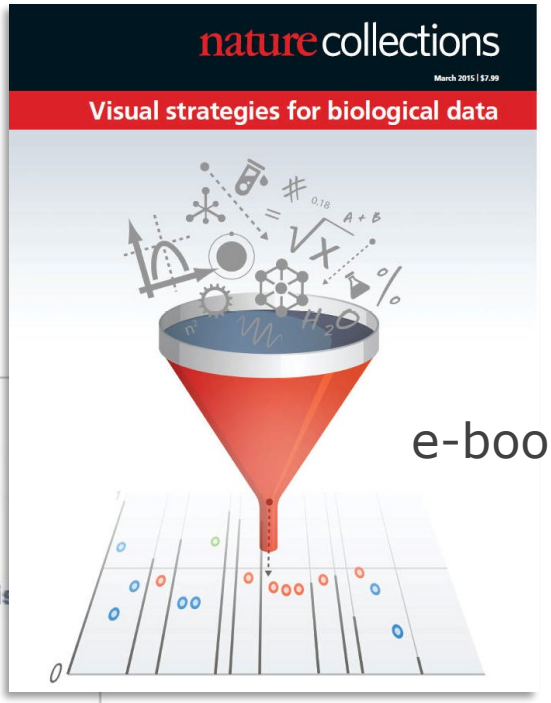
Top picks from nature news

Nature News | News

Scientific method: Statis errors

Regina Nuzzo

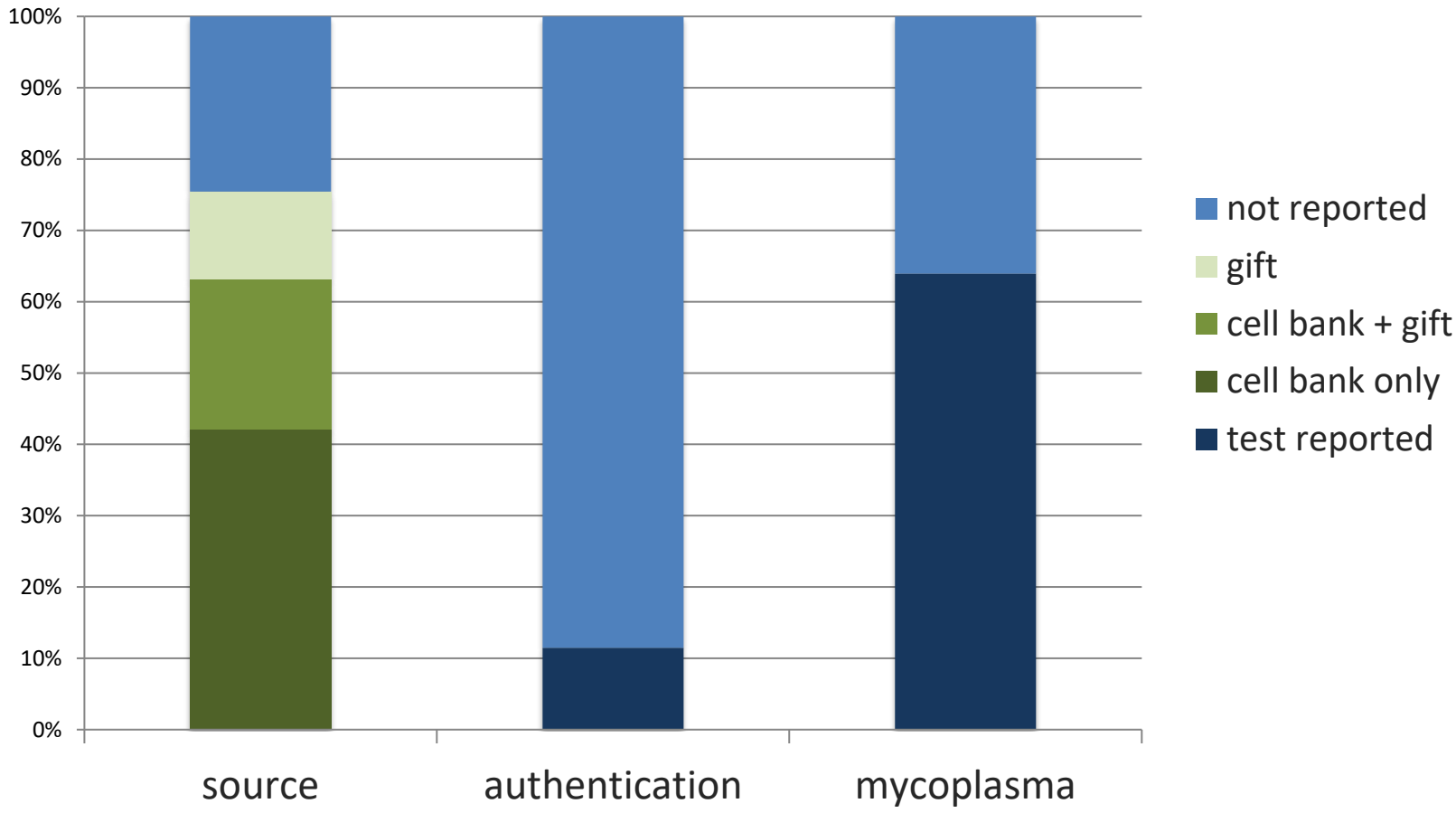
free web collection (incl. *Nature Methods* 'Points of Significance' columns)



e-book

Reporting cell line characterization

Multiple Nature journals



n = 60 papers that report the use of cell lines

Reagents definition

Cell line identity policy – April 2015

ANNOUNCEMENT

Time to tackle cells' mistaken identity

The differences between a cow and a monkey are clear. It is easy to tell a moth from a mosquito. So why are there still scientific studies that mix them up? The answer is simple: hundreds of cell lines stored and used by modern laboratories have been wrongly identified. Some pig cells are labelled as coming from a chicken;

Problems have already ...0 cell lines. In the long term, the goal ...ines world-wide to ensure that new n... ...e least that scientists should already ... ...the cell line they are using is one of th... ...d flag.

In 2013, Nature journals started to ask authors to report the source of their cell line and whether the cell line had been authenticated. Most have not done so. Out of a sample of around 60 cell-line-based papers published across several Nature journals in the past two years, almost one-quarter did not report the source. Only 10% of authors said that they had authenticated the cell line. This is especially problematic given that almost one-third said that

ANALYSIS

doi:10.1038/nature14397

A resource for cell line authentication, annotation and quality control

Mamie Yu[1]*, Suresh K. Selvaraj[1]*, May M. Y. Liang-Chu[1], Sahar Aghajani[2], Matthew Busse[2], Jean Yuan[2], Genee Lee[1], Franklin Peale[3], Christiaan Klijn[2], Richard Bourgon[2], Joshua S. Kaminker[2] & Richard M. Neve[1]

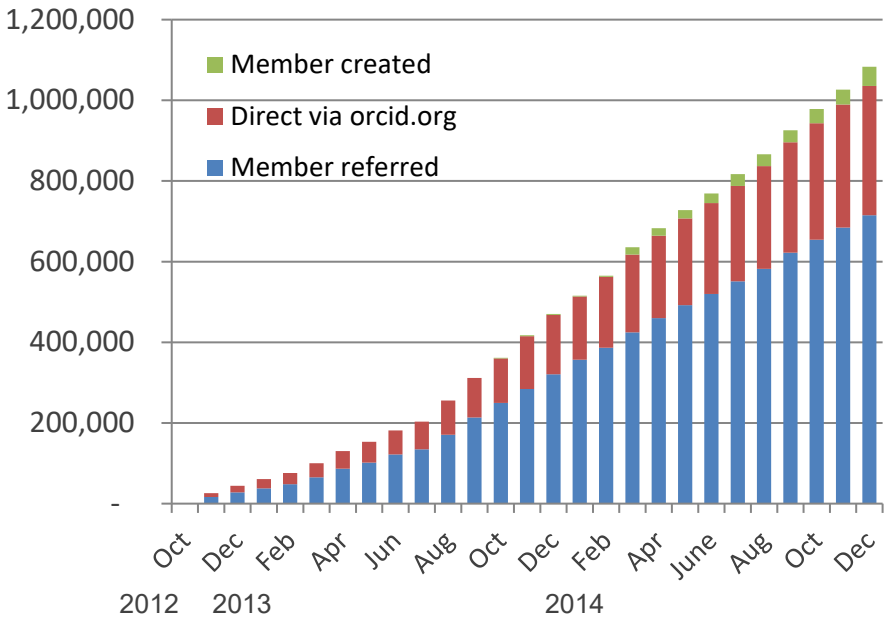
Journals and publishers can help facilitate credit for all contributions

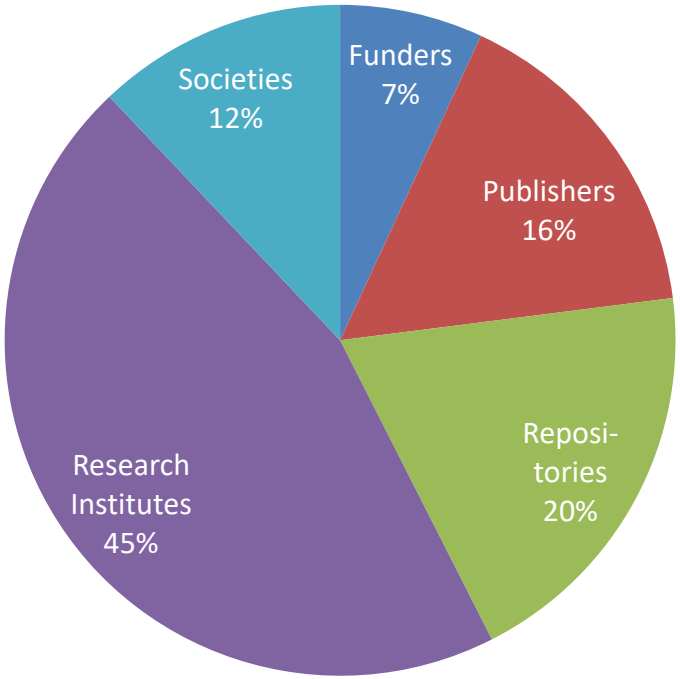
Publishers support community initiatives

ORCID
Connecting Research and Researchers

ORCID is a non-for-profit organization supported by publishers, funders, universities, professional societies, researchers associations.

ORCID provides persistent unique identifiers to researchers





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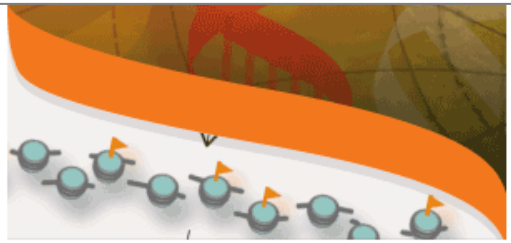
Mutations in the gene encoding PDGF-B cause brain calcifications in humans and mice



Annika Keller, Ana Westenberger, Maria J Sobrido, Maria García-Murias, Aloysius Domingo, Renee L Sears, Roberta R Lemos, Andres Ordoñez-Ugalde, Gael Nicolas, José E Gomes da Cunha, Elisabeth J Rushing, Mi
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Miyasaki, Irina Abakumova, Maa
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Affiliations | Contributions | Corresponding authors

Nature Genetics **45**, 1077–1082 (2013) | doi:10.1038/ng.2723

Received 05 April 2013 | Accepted 12 July 2013 | Published online 04 August 2013

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3rd Sardinian Summer School Genomic Analysis of Complex and Monogenic Disorders, 3rd

Author contributions

Project CRediT: a taxonomy of contributions

Nature journals have mandated author contribution statements since 2009, to clarify credit and accountability

Now working with other publishers, funders and scientists to establish a standardized vocabulary of contributions

ORCID
Connecting Research and Researchers

CRediT
An open standard for expressing roles intrinsic to research


COMMENT

Credit where credit is due

Liz Allen, Amy Brand, Jo Scott, Micah Altman and Marjorie Hlava are trialling digital taxonomies to help researchers to identify their contributions to collaborative projects.

Writing

Investigation

Formal analysis

Research today is rarely a one-person job. Original research papers with a single author are — particularly in the life sciences — a vanishing breed. Partly, the inflation of author numbers on papers has

Through the endorsement of individuals' contributions, researchers can start to move beyond 'authorship' as the dominant measure of esteem. For funding agencies, better information about the contributions of grant applicants would aid the decision-making

journal articles could be classified using a 14-role taxonomy (see 'Who did what?'). The survey was sent to 1,200 corresponding authors of work published in PLOS journals, Nature Publishing Group journals, Elsevier journals, *Science* and *eLife*. Corresponding authors were asked to indicate the contribu-

CASRAI | NISO standard
Wellcome Trust | Digital Science

Data journals

Credit for production and sharing of reusable data

SCIENTIFIC DATA

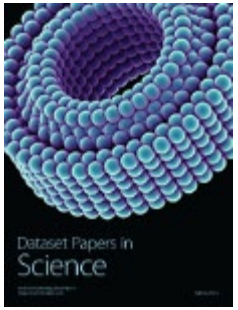
(GIGA)n SCIENCE

F1000 Research

Earth System Science Data

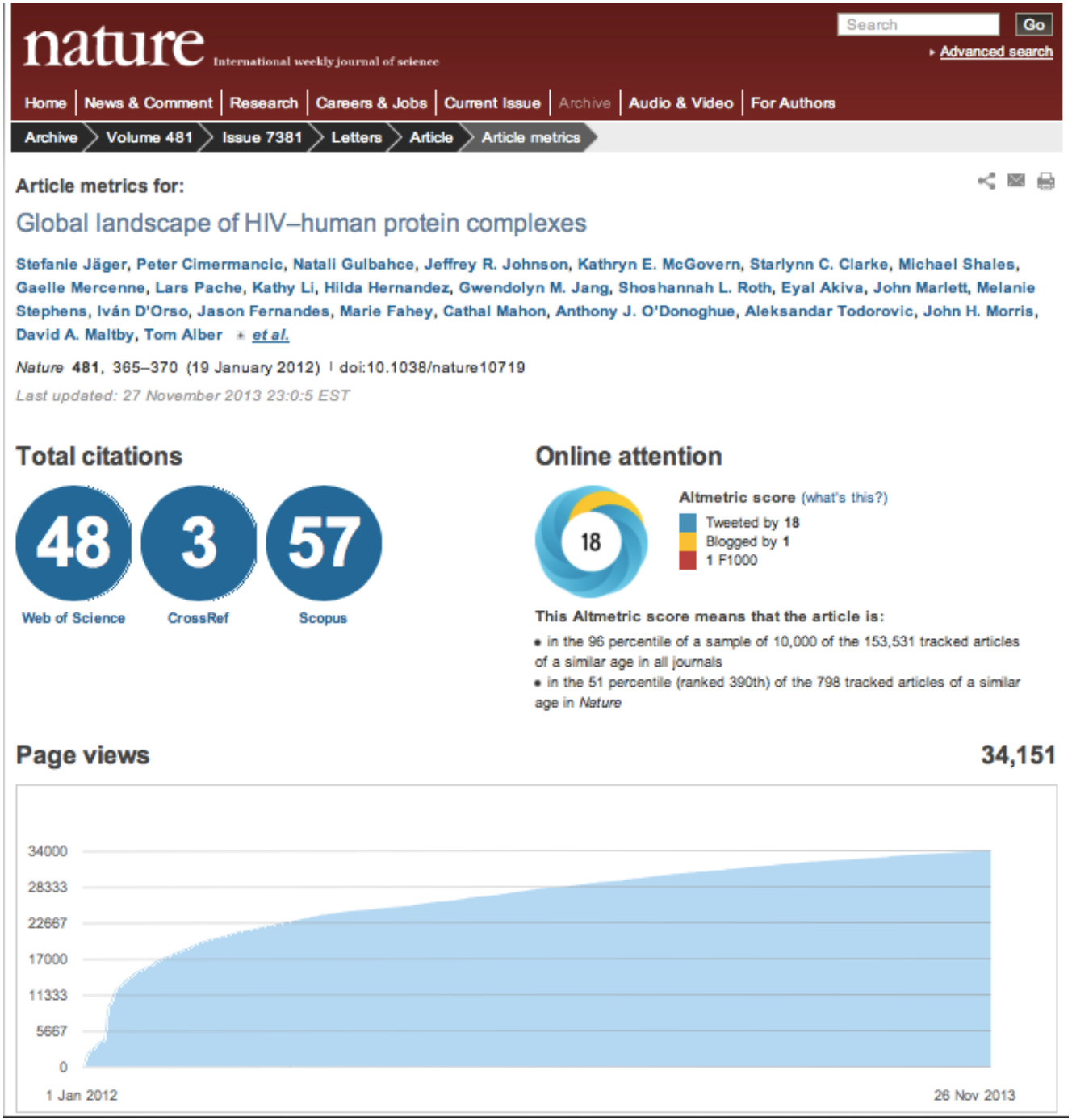
open health data

BMC Research Notes



DATA IN BRIEF
MAKE YOUR DATA COUNT

A peer-reviewed open-access journal
Biodiversity Data Journal
Making your data count! ISSN 1314-2828 (online)



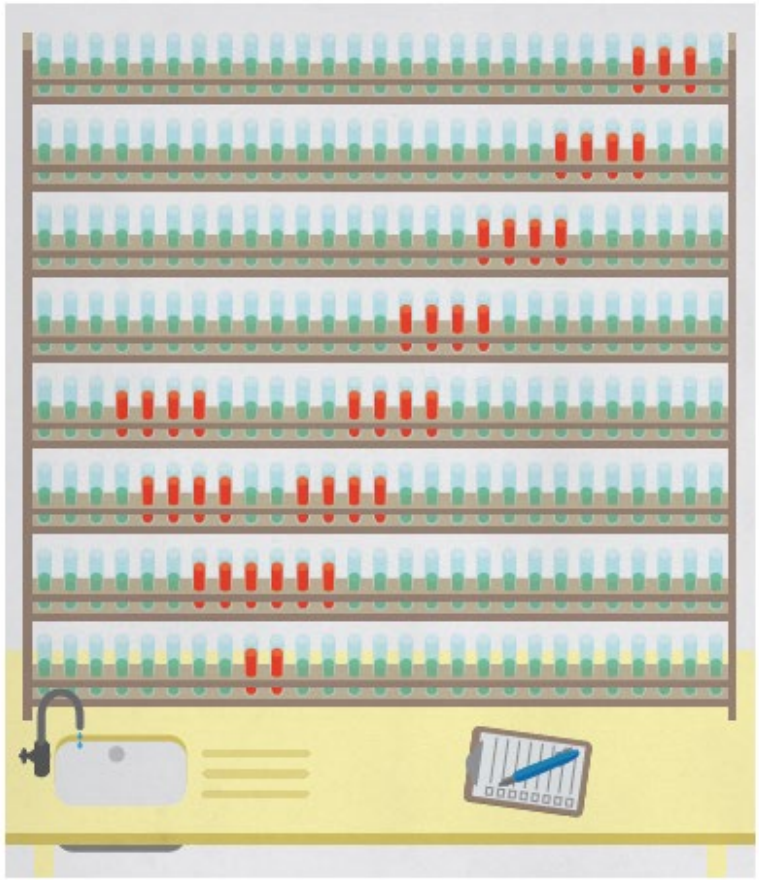
Article-level metrics

Alternative measures of interest and impact

Role of journals

- Raise awareness
- Be a catalyst and facilitator of discussions
- Drive some changes
- Ensure full reporting, effective review and measured conclusions
- Provide opportunities for detailed and accurate credit for all contributions
- Respond quickly and thoroughly to criticisms of published papers

Role of funders



NIH plans to enhance reproducibility

Francis S. Collins and **Lawrence A. Tabak** discuss initiatives that the US National Institutes of Health is exploring to restore the self-correcting nature of preclinical research.

NIH actions:

- training focused on good experimental design http://www.nih.gov/science/reproducibility/
- test checklist for more systematic evaluation of grant applications, incl. evaluation of scientific premise
- greater transparency of data underlying published papers
- PubMed Commons for open discussion about published articles
- new biosketch format for grant applications

Role of funders

RCUK demand strong statistics for animal studies

Home / Press and Media / News and Announcements / Updated RCUK guidance for funding applications involving animal research

Updated RCUK guidance for funding applications involving animal research

Funders and the peer review process have an important role in assessing the validity, necessity and justification of research grant proposals in relation to the funding body's research strategy and ethical framework. When research involving animals is proposed, funders have a duty to assess as part of the peer review the need to use animals, the appropriateness of the species and model chosen, and robustness of the planned experimental design and statistical framework.

The Research Councils and the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs) have reviewed and aligned their guidance to clarify for researchers what information they are expected to provide to allow robust evaluation of applications for funding involving animal research.

- justify the work and set out ethical implications
- demonstrate that the experimental design is statistically robust

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Universities and institutions: target issues

- Training
- Oversight and compliance with best practices
- Laboratory size & PI time for mentoring and support
- Infrastructure and support
  - data management, reagents, validation services
  - quality assurance support
- Incentives and recognition for good laboratory leadership

Thank you for listening

My thanks to colleagues:

- Philip Campbell
- **All Nature journals editors** for their efforts in implementing reproducibility measures

- Kalyani Narasimhan for leading in neuroscience
- Daniel Evanko for statistics resources
- Hugh Ash for impact study

- Malcolm McLeod (Edinburgh) and CAMARADES team for impact study
- Amy Brand (Digital Science) and Liz Allen (Wellcome Trust) for CRediT

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