THE LANCET Oncology

Medical Publishing and How to Get Published

Insights From an Editor

David Collingridge, PhD
Editor-in-Chief, *The Lancet Oncology*
Publishing Director, *The Lancet* Group

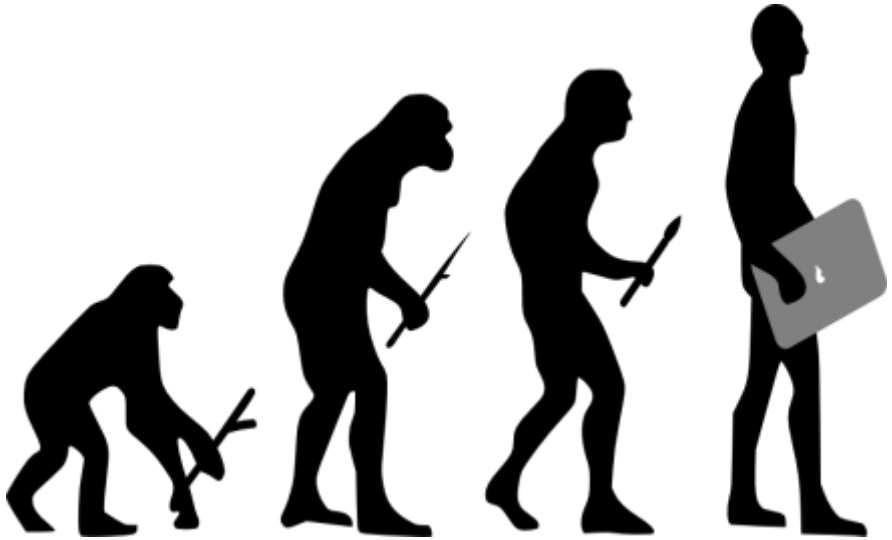
Clinical Associate Professor of Radiation Medicine
Hofstra/Northwell Health, Lake Success, NY, USA

125 London Wall
London
EC2Y 5AS
United Kingdom
david.collingridge@lancet.com

Northwell Health

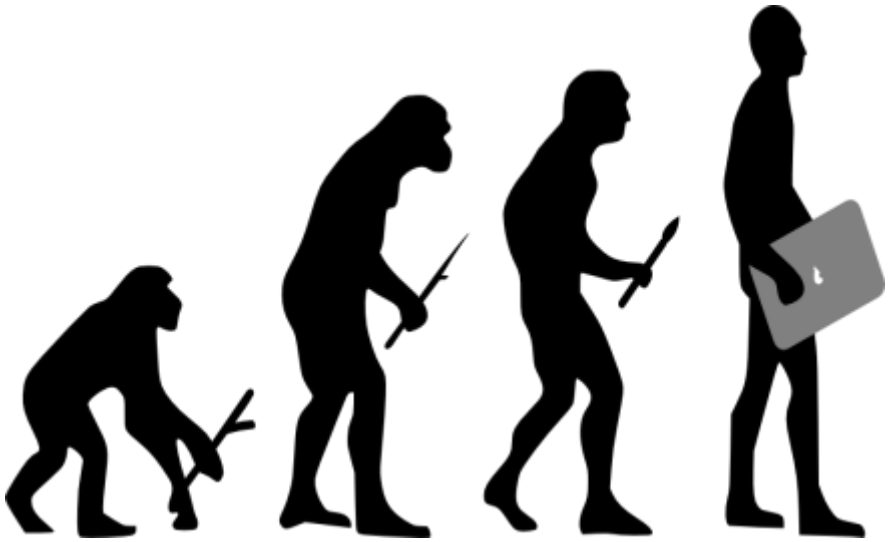
DONALD AND BARBARA ZUCKER SCHOOL of MEDICINE AT HOFSTRA/NORTHWELL

The Lancet through the ages and drivers of change

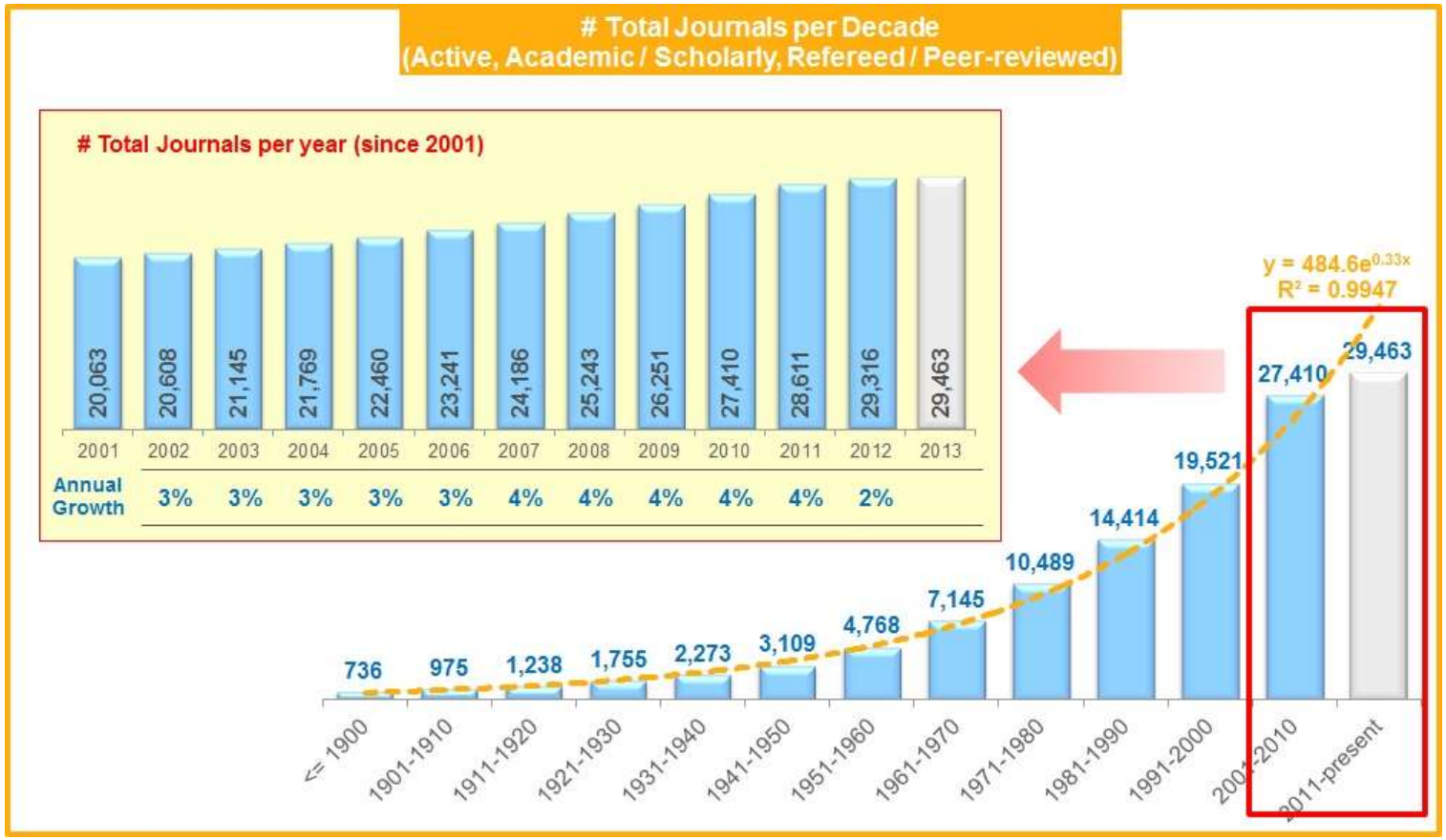


Getting published successfully (what Editors look for)

The Lancet through the ages and drivers of change



Numbers of journals increasing rapidly

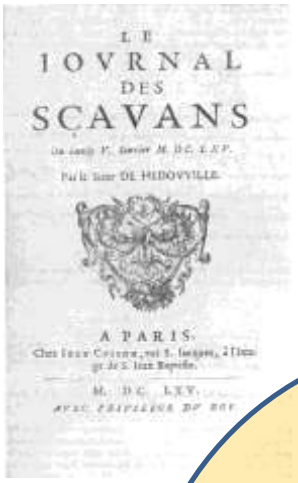


Growth in peer-reviewed journals, 1900-2013. Source: Researcher Academy, Elsevier

Science and medical publishing through the ages

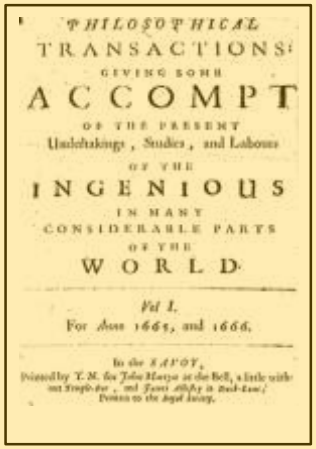
Ca. 1500 BC

Edwin Smith Papyrus: first description of breast cancer surgery



January 1665

March 1665

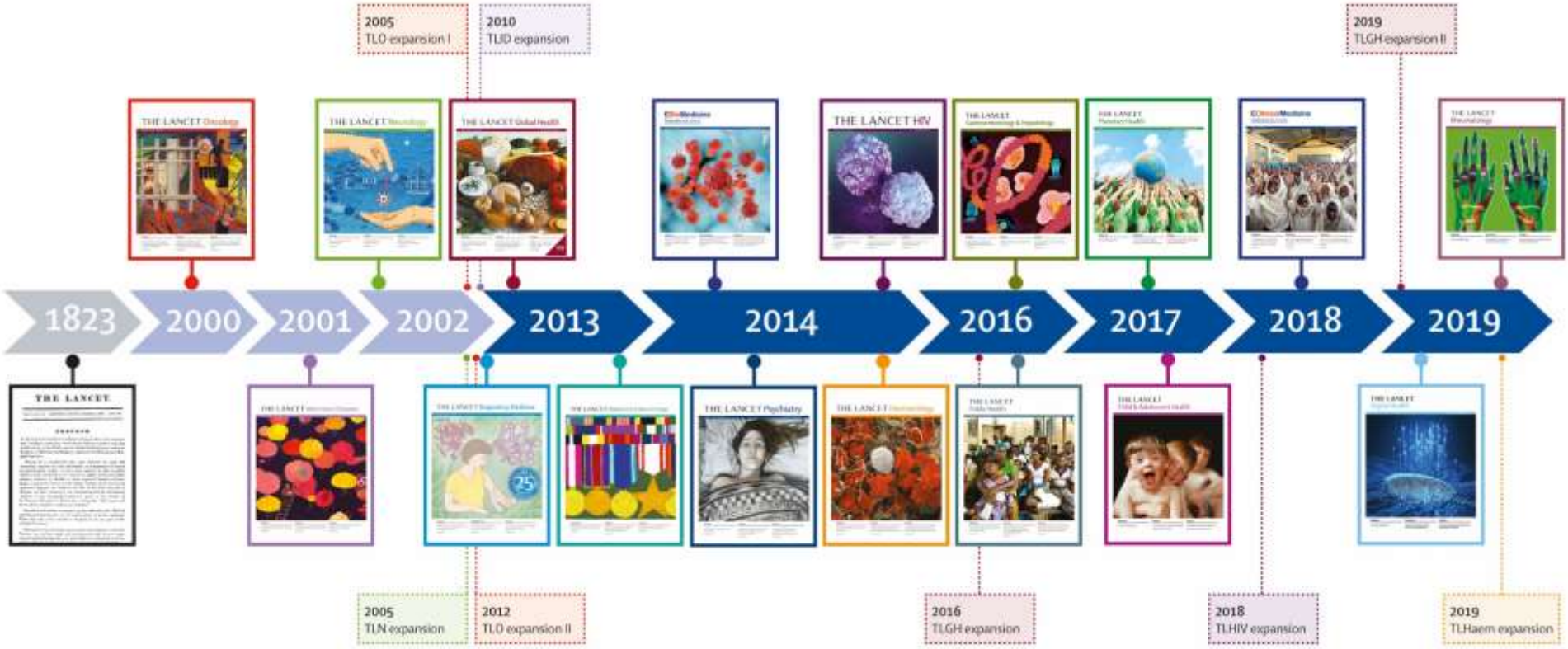


July 1797

January 1812

October 1823

The Lancet Portfolio



Who are we, what motivates us?

We are a family of medical science journals committed to:

THE BEST SCIENCE FOR BETTER LIVES

- We stand for high quality and reliable medical science
- We are vigilant, responsive, and fast
- We are more than a collection of journals
- We are annoyed about the health disparities in our world
- We campaign for health equity and the right to health
- We are political
- We hold those in power accountable for their promises
- We are advocates and activists for health justice

Founding of The Lancet

October 5, 1823

Thomas Wakley, founding Editor of The Lancet, member of Parliament, and coroner was a radical reformer of the Victorian age

He founded The Lancet to root out corruption and quackery, and to challenge the medical establishment

The Lancet was, and still is, registered as a ‘newspaper’; as a journalistic endeavour, we have a duty to hold institutions, people, science, and medicine accountable for their actions

Founding of The Lancet

A Lancet "can be an arched window to let in the light, or it can be a sharp surgical instrument to cut out the dross, and I intend to use it in both senses."
Thomas Wakley, 1823

Some Lancet 'firsts'

- First successful blood transfusion (1829)
- First description of chloroform an anaesthetic (1847)
- Artificial respiration (1856)
- Lister's theory of antisepsis (1867)
- Letter from Florence Nightingale on poor sanitation in India (1870)
- Nitro-glycerine for angina (1879)
- First use of x-rays (1896)
- Use of new 'hypnotic': heroin (1898)
- First publication from China (1911)
- Description of shell shock (aka, PTSD) (1918)
- Importance of medical statistics (1936)
- First test for tuberculosis (1951)
- Blood typing (1956)
- Thalidomide and birth defects (1961)
- Foetal alcohol syndrome (1973)
- Introduction of Glasgow Coma Scale, still in use today (1974)
- First "test tube baby" (1978)
- First use of MRI (1981)
- Discovery of *Helicobacter pylori* (1983)
- Use of statins for prevention of heart disease (1994)
- Creutzfeldt-Jakob syndrome (1996)
- Intensive blood glucose control for diabetes (1998)
- Causative agent of SARS (2003)
- Ebola vaccine (2015)

Organised science can provide a strong platform for health (and political) advocacy

Mission statement

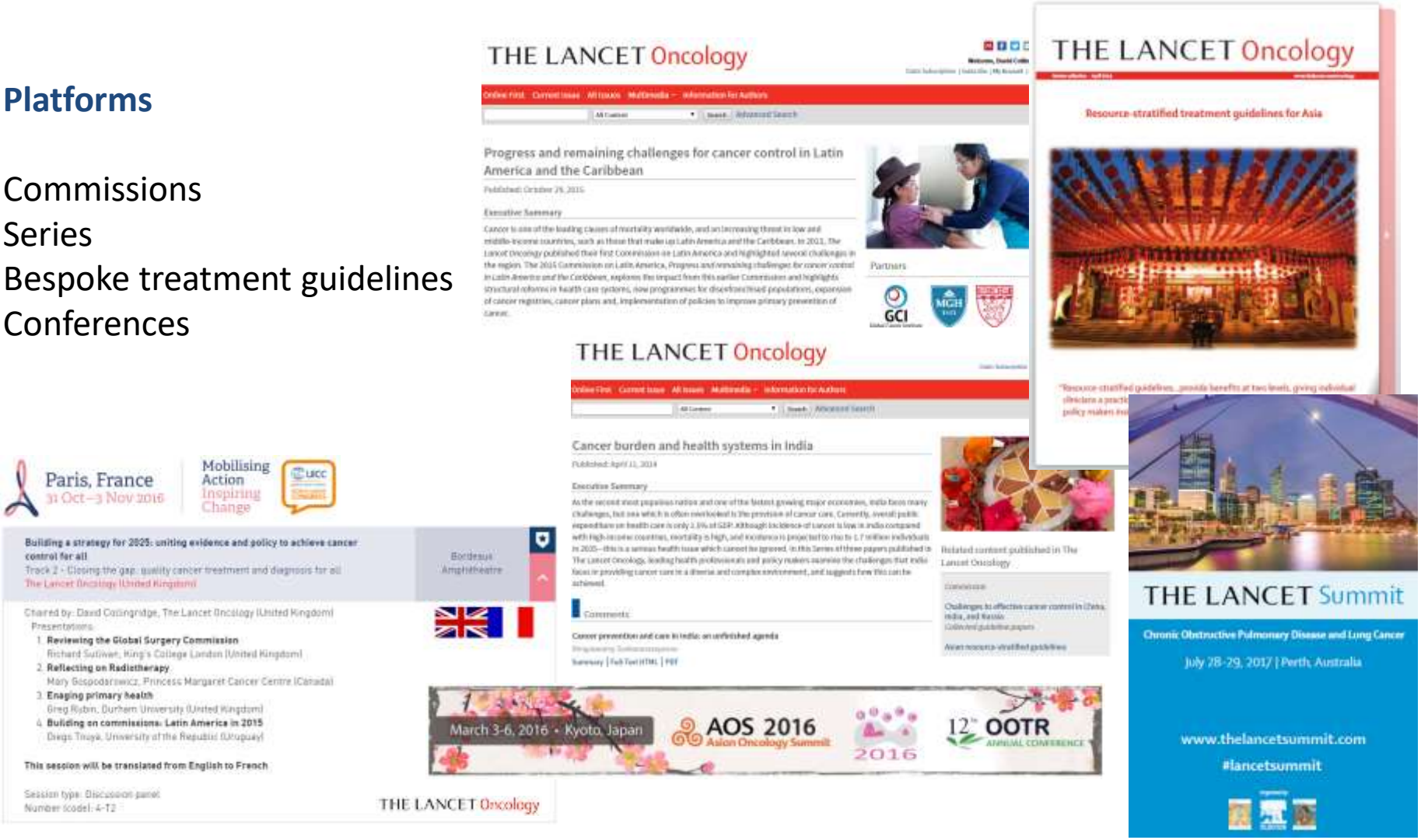
The Lancet Oncology's global advocacy programme maps out the inequalities and inequities in health systems worldwide, and highlights deficiencies in all aspects of cancer care, health policy, structural organisation, and leadership.

The programme offers a neutral platform to bring together thought-leaders from across different disciplines and organisations to offer solutions to those barriers that hinder provision of high quality cancer control, irrespective of socioeconomic status or country of residence.

We aim to use the journal's international and influential voice to deliver the *best science for better lives*.

Platforms

Commissions
Series
Bespoke treatment guidelines
Conferences



THE LANCET The best science for better lives

More than a journal: Commissions

The Lancet Oncology's Commissions programme

Goal

Highlight and provide solutions for inequities in two domains:

- The patient journey from prevention through to end of life
- Global cancer control and regional variation

Commissions

Four ongoing for launch 2019-21

Integration of oncology and palliative care: a *Lancet Oncology* Commission
Kaasa S, et al
2018

Future Cancer Research Priorities in the USA
Jaffee E, Van Dang, C, et al
November 2017

Progress and remaining challenges for cancer control in Latin America and the Caribbean
Strasser-Weippl et al
October, 2015

The expanding role of primary care in cancer control
Rubin et al
September, 2015

Global cancer surgery: delivering safe, affordable, and timely cancer surgery
Sullivan et al
September, 2015

Expanding global access to radiotherapy
Atun et al
September, 2015

Challenges to effective cancer control in China, India, and Russia
Goss et al
April, 2014

Planning cancer control in Latin America and the Caribbean
Goss et al
April, 2013

Delivering affordable cancer care in high-income countries
Sullivan et al
September, 2011

The Lancet Oncology's Cancer Control Hub

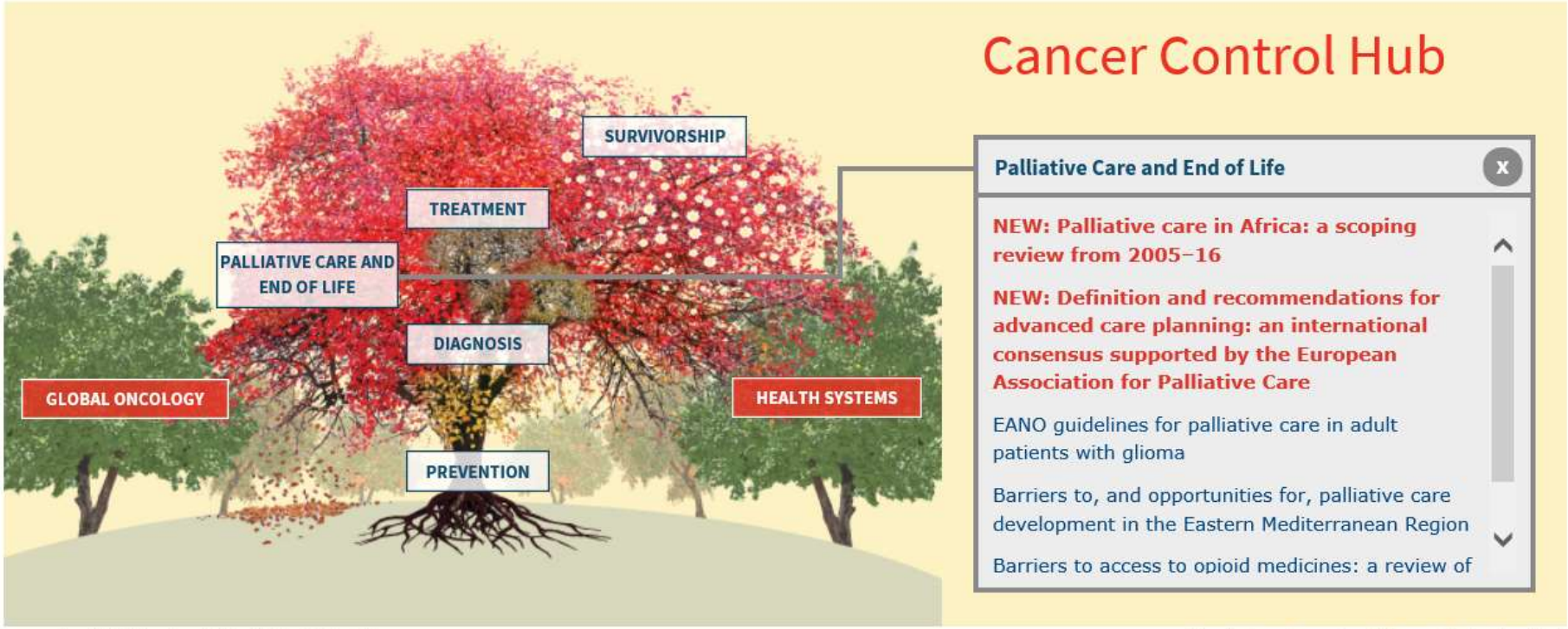


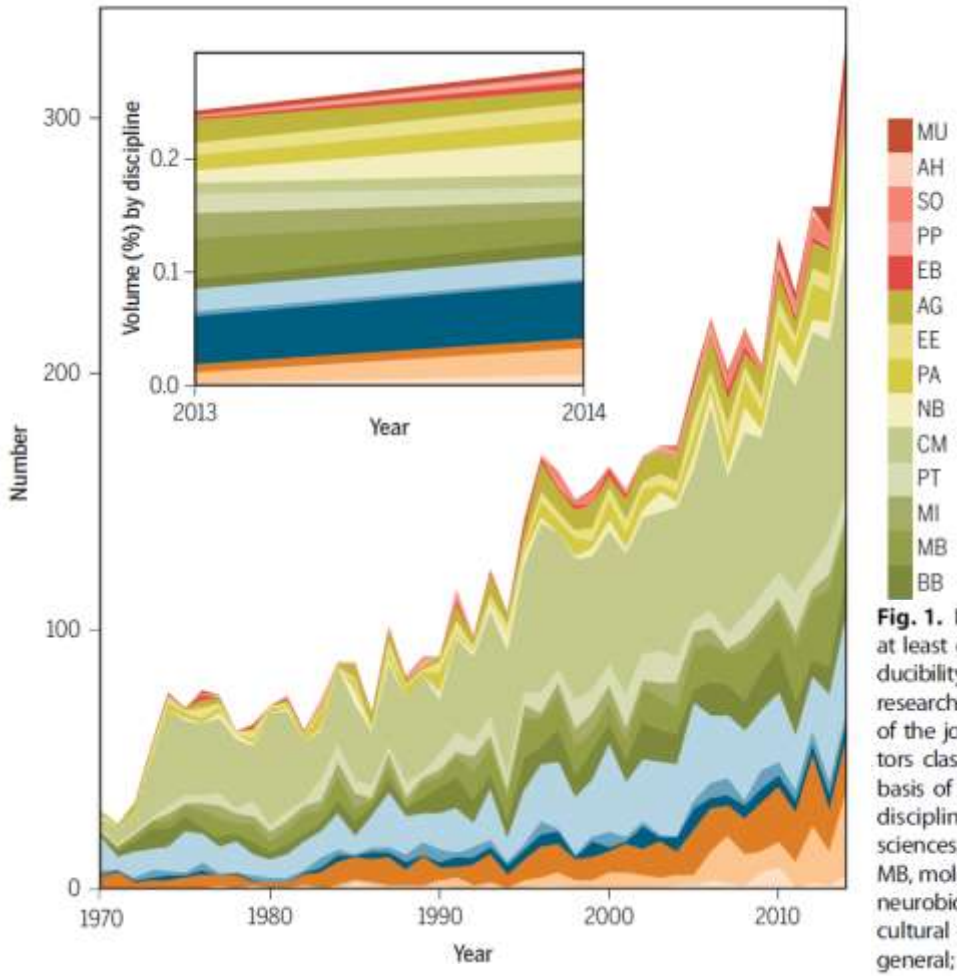
Image Credit: Adrian Roots/Paul Price/Debut Art

View text-only version of Cancer Control content

Key developments shaping research and publishing

- Data reproducibility
- Open access
- Data-sharing
- Preprint servers

Data reproducibility and research waste



Clinical Medicine: concern about trust rapidly increasing over time

SCIENTIFIC INTEGRITY

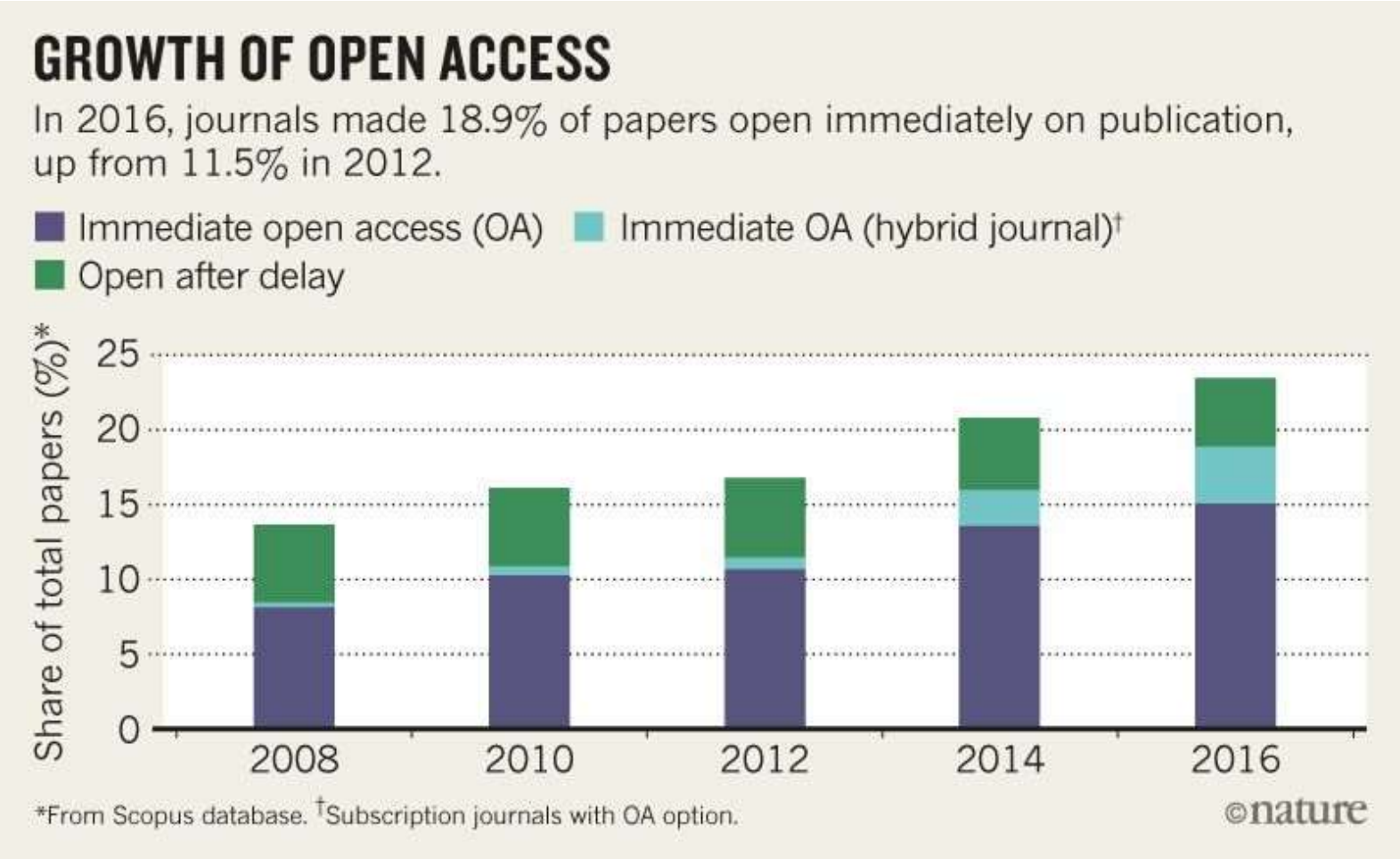
What does research reproducibility mean?

Steven N. Goodman,* Daniele Fanelli, John P. A. Ioannidis

www.ScienceTranslationalMedicine.org 1 June 2016 Vol 8 Issue 341 341ps12

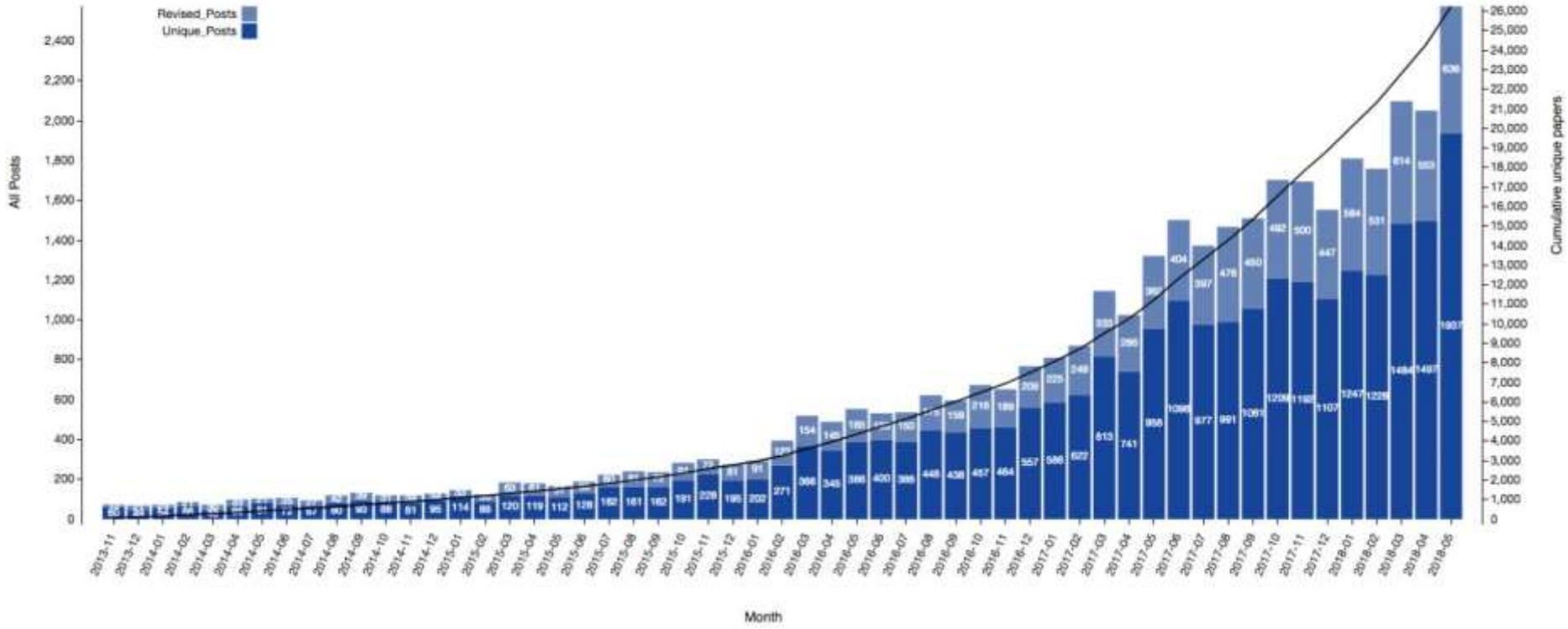
Fig. 1. Reports rising. Number of publications recorded in Scopus that have, in the title or abstract, at least one of the following expressions: research reproducibility, reproducibility of research, reproducibility of results, results reproducibility, reproducibility of study, study reproducibility, reproducible research, reproducible finding, or reproducible result. Papers are classified by discipline on the basis of the journal, following an adaptation and expansion of Thomson Reuters' Essential Science Indicators classification system. Journals not included in the latter database were hand-classified on the basis of their name. The subplot reports the percentage over the total number of records for each discipline, in the last 2 years of the series. Disciplines legend: MA, mathematics; CS, computer sciences; EN, engineering; SP, space science; PH, physics; CH, chemistry; BB, biology and biochemistry; MB, molecular biology; MI, microbiology; PT, pharmacology and toxicology; CM, clinical medicine; NB, neurobiology and behavior; PA, plant and animal sciences; EE, environment and ecology; AG, agricultural sciences; EB, economics and business; PP, psychology and psychiatry; SO, social sciences, general; AH, arts and humanities; MU, multidisciplinary. The time series was truncated at 2014.

Growth in gold open access

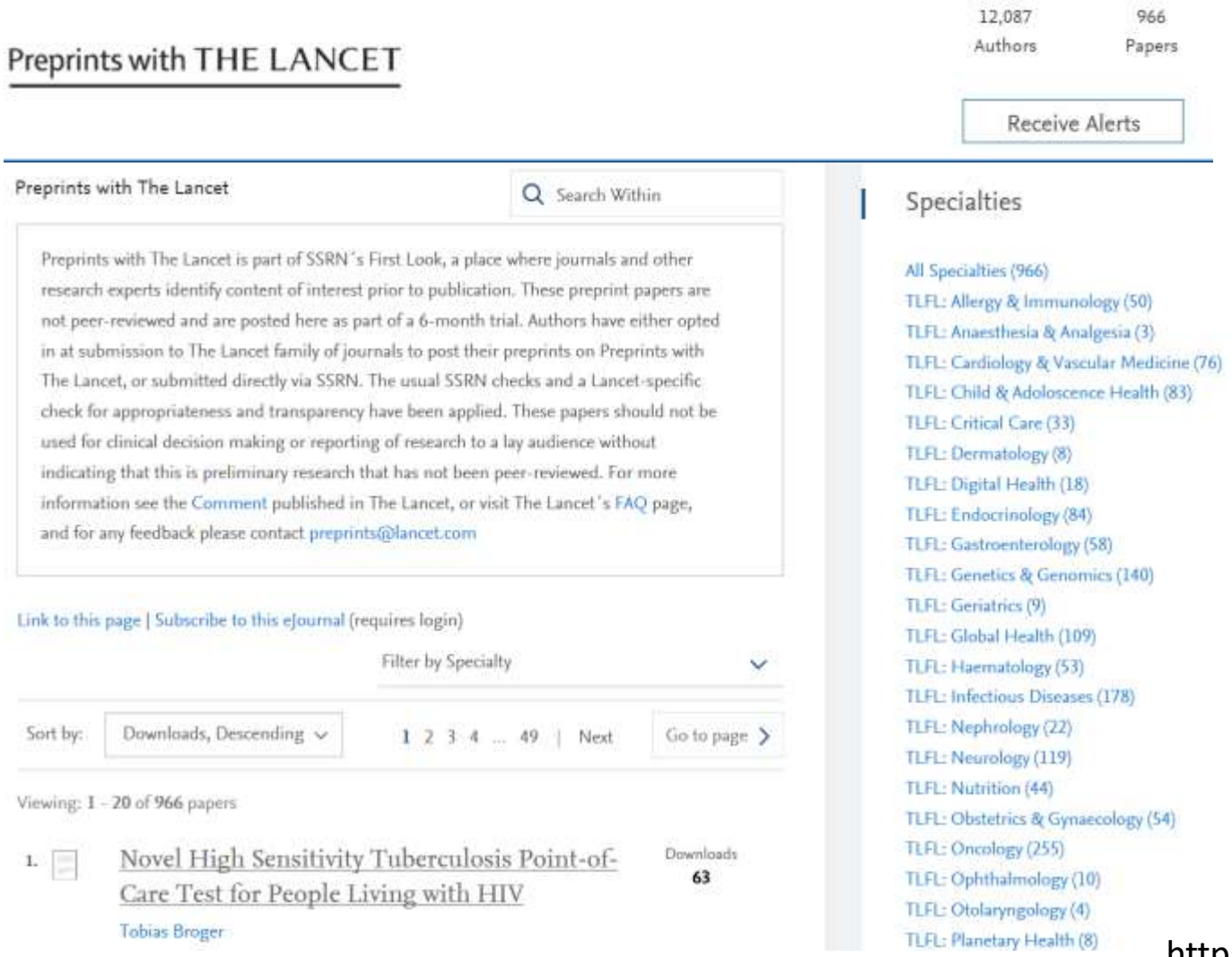


Preprint servers: another way of improving free access to the latest science

Growth in content in BioRxiv



Preprint servers: another way of improving free access to the latest science



https://www.ssrn.com/en/

Preprints: some facts

- Preprints are scholarly manuscripts posted by the author in an open accessible platform, usually before, or in parallel with, the peer review process
- Increasing numbers of funders encourage preprints (Wellcome Trust, MRC, NIH)
- The Lancet family of journals are the first to launch medical preprints (research only) in partnership with SSRN
- As of the February 13, 2019: 1744 articles posted, 17,625 authors, 9,314 downloads
- Caution: preprints should not be used for clinical decision-making or reporting research findings to a lay audience without indicating they are preliminary research that has not been peer-reviewed

THE LANCET Oncology

Data-sharing: position of medical journals

1 As of July 1, 2018, manuscripts submitted to ICMJE journals that report the results of clinical trials must contain a data sharing statement as described below.

2 Clinical trials that begin enrolling participants on or after Jan 1, 2019, must include a data sharing plan in the trial's registration. The ICMJE's policy regarding trial registration is explained on the ICMJE website.

Comment

Data sharing statements for clinical trials: a requirement of the International Committee of Medical Journal Editors

The International Committee of Medical Journal Editors (ICMJE) believes there is an ethical obligation to responsibly share data generated by interventional clinical trials because trial participants have put themselves at risk. In January, 2016, we published a proposal aimed at helping to create an environment in which the sharing of de-identified individual participant data becomes the norm.[1] In response to our request for feedback we received many comments from individuals and groups. Some applauded the

It is encouraging that data sharing is already occurring in some settings. Over the past year, however, we have learned that the challenges are substantial and the requisite mechanisms are not in place to mandate universal data sharing at this time. Although many issues must be addressed for data sharing to become the norm, we remain committed to this goal.

Therefore, the ICMJE will require the following as conditions of consideration for publication of a clinical trial report in our member journals:

Published Online
June 5, 2017
http://dx.doi.org/10.1016/S0140-6736(17)31282-5

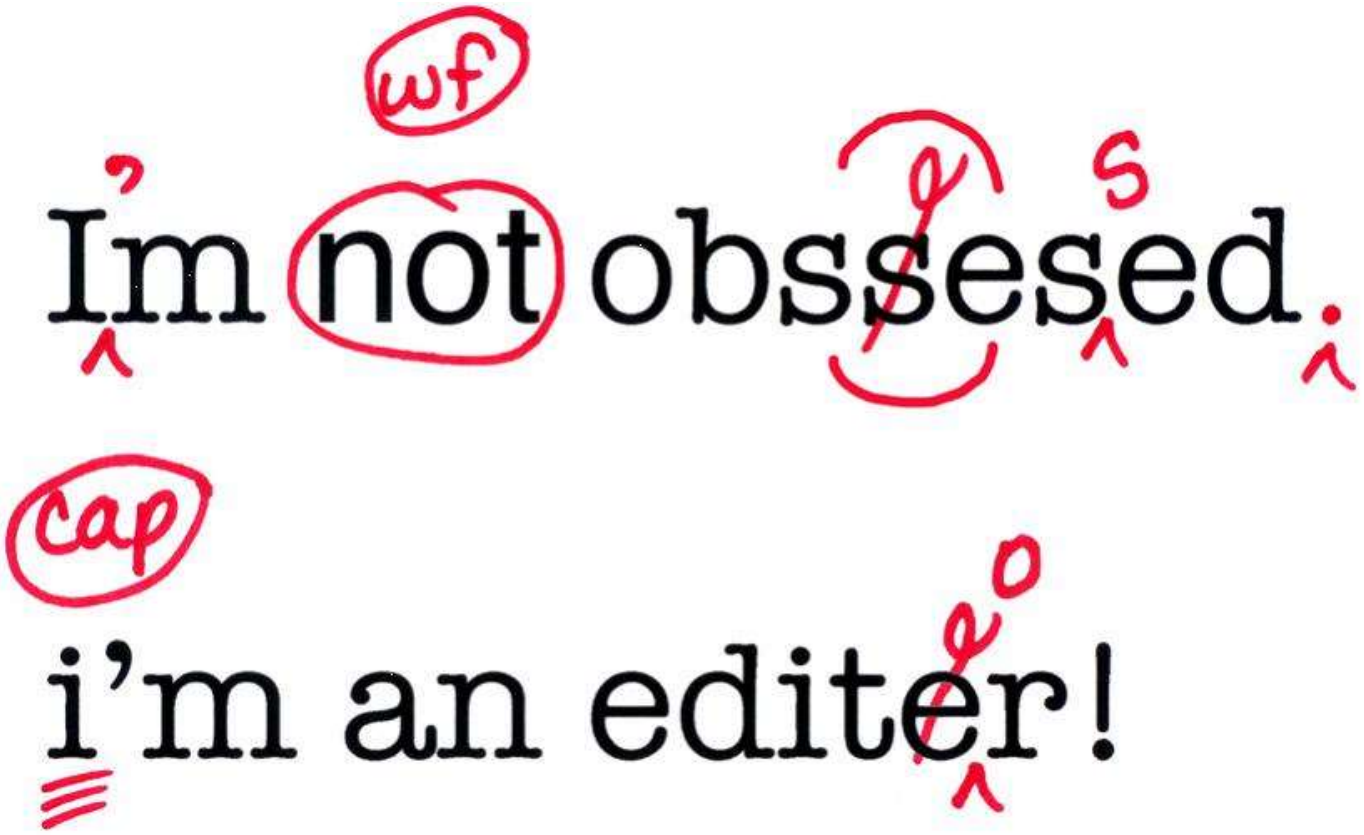
For ICMJE's website see www.icmje.org

For ICMJE's policy regarding trial registration see www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html

Data-sharing: some reflections

- Ethical obligation for data-sharing as trial participants have placed themselves at risk
- Shared data might provide observations that would not have been seen
- Shared data will increase the confidence and trust in research conclusions by allowing independent validation
- Will hasten research speed and effectiveness while simultaneously reducing research waste
- Reduces risk for future patients (increased knowledge leading to better trial designs, and reduction in numbers of patients needed to be enrolled in trials)

Getting published successfully
(what Editors look for)



Keys to a successful publication

- Answering the right question in the right way at the right time
- Making your submission as compelling as possible
- Writing in an accessible manner
- For research always following the basic rule: IMRAD—Introduction, Methods, Results, and Discussion

Why publish?

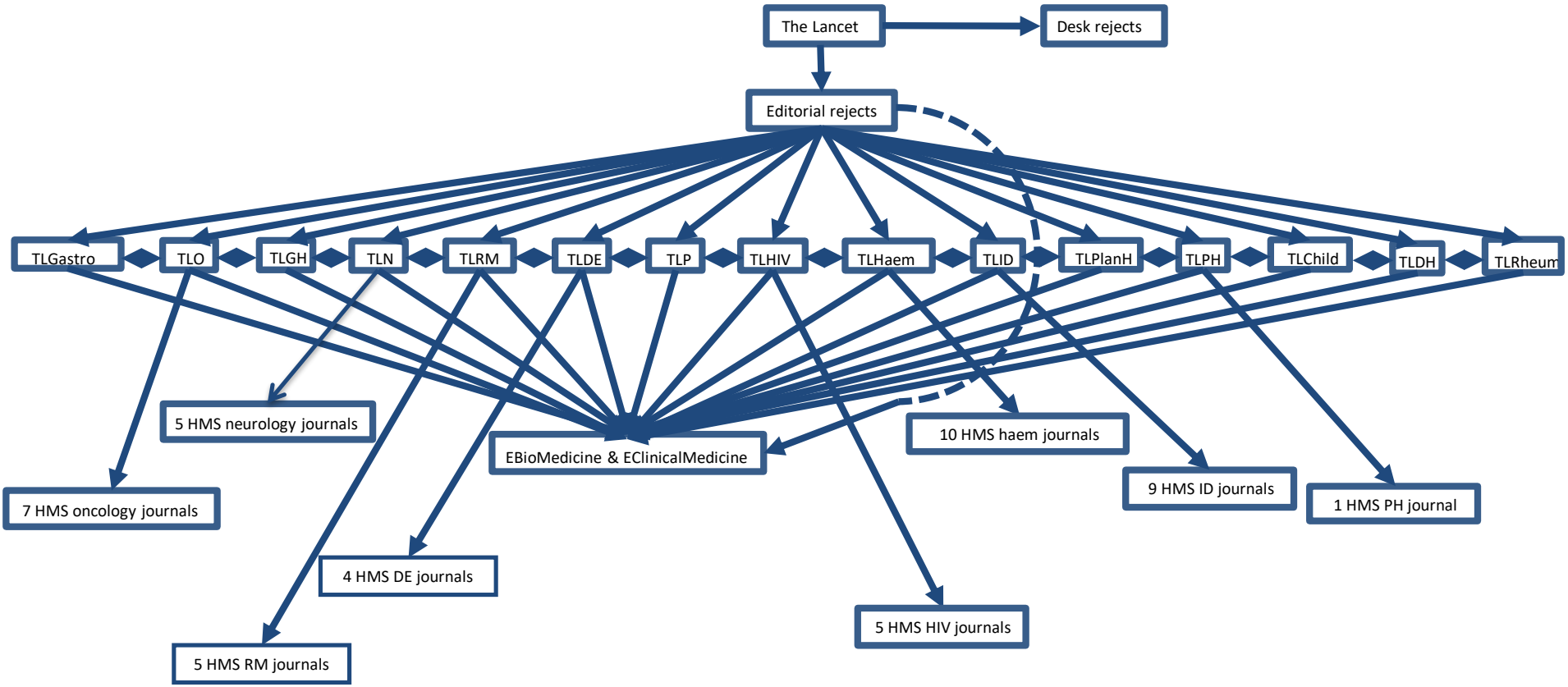
The positives:

1) To influence thinking and clinical practice
2) To improve patient outcomes
3) Personal recognition
4) To prove your work is a high calibre
5) As professional obligation to society
6) To access a privilege your work affords you
7) For personal challenge
8) Improve career prospects

The negatives:

1) Takes time away from core activities
2) Opens yourself up to criticism and judgment by others
3) Can lead to rejection
4) Can be stressful

Journal collaborations and cascade workflows at The Lancet Group



What do top-ranking journals publish?

- Novel work
- First and last
- Practice-changing
- Challenges convention or dogma
- Largest dataset to-date (with different or definitive results to all other papers)
- Robust methodology
- Not just positive results, some negatives are very important
- Clinical trials
- Large meta-analyses
- Topic relevant to a large demographic
- Messages that are not regionally or geographically limited

Common barriers to publication

Examples include…

Lack of novelty
Poorly defined objectives
Inappropriate analyses
Findings not validated, independently
Biased and illogical reporting
Poorly conceived arguments and discussion
'Me too' syndrome
Subject too specialised
Topic or article out of scope of chosen journal
Very poor presentation and use of language hindering understanding

Mathematical errors also affect success

Examples include…

Insufficient numbers to address objectives with confidence
Inappropriate analyses
Inconsistent reporting of data, or of facts and figures, throughout a paper
Over-emphasising interpretation of certain data or facts and figures
Lack of a prespecified statistical plan
Over-reliance on ad-hoc, exploratory analyses
Use of wrong statistical tests for comparisons
Use of outmoded analytics
Over-reliance on very rare, perhaps unvalidated, analytical tests

And sometimes…

Data that seem to be ‘to good to be true’

What editors look for: general points

Does the topic or article type fall within the scope of the journal?
Is the topic important and timely?
Is the study interesting to our readers?
Does the study have potential to change clinical practice?
Does the study have a sound hypothesis and design?
Is it appropriately powered statistically?
Is the study analysed properly?
Are missing data handled appropriately?
Is the interpretation a fair reflection of the results?
For trials: does study have a protocol?
For trials: are main analyses presented protocol-defined?
For trials: are non-protocol (exploratory) analyses signposted?
For trials: is it registered?

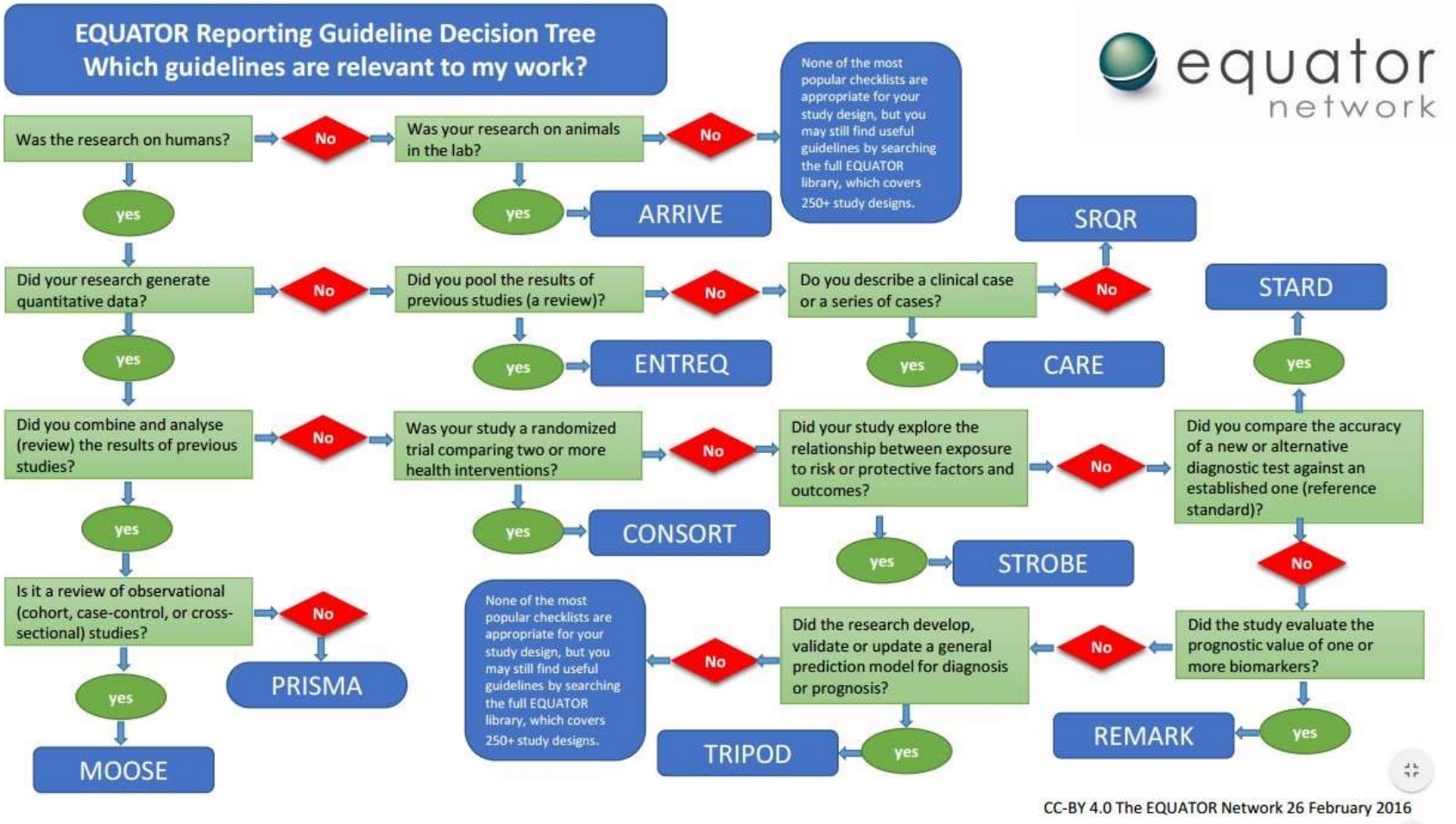
What editors look for: general points

Has the paper been written according to Information for Authors?
For Lancet journals: does is contain a Research in Context panel (systematic review; interpretation)
For Lancet journals: does it contain Search Strategy and Selection Criteria panel
Is writing style concise and well ordered?
Have appropriate reporting standards been used?
Have authors clearly stated the need for this study in context?
Is the paper a salami slice?

What editors look for: Quality of life & patient-reported outcomes

Is QOL/PRO a valid endpoint in this study?
Is QOL/PRO protocol defined?
Is QOL/PRO measured with a validated instrument?
Do results represent an appropriate proportion of patients?
Should QOL/PRO data be presented with other endpoints?
Are data analysed and interpreted correctly?
Is result powered statistically, and if not, why not?
Is the result clinically relevant?

What editors look for: use of reporting standards



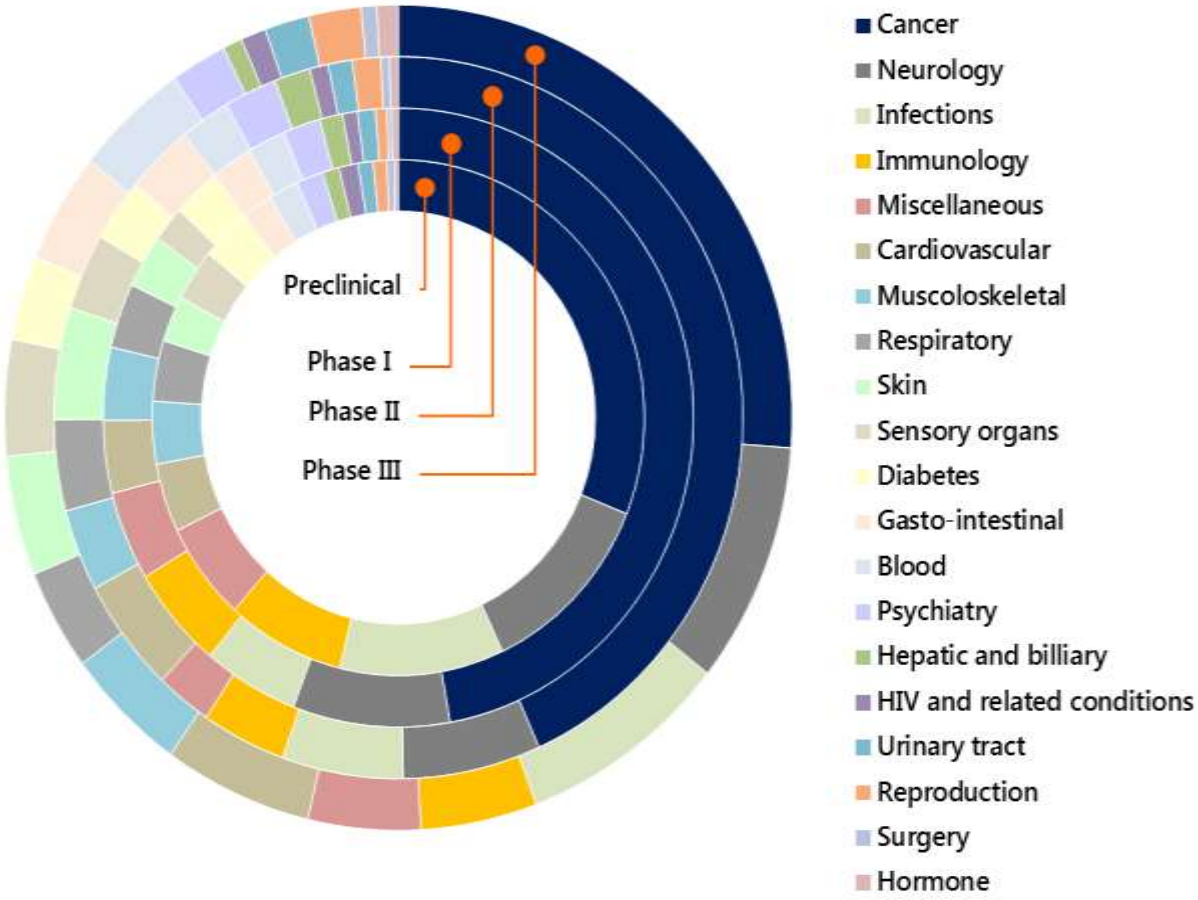
Clinical trial registration: why important?

Promotes transparency in reporting
Highlights those trials that might never report
Identifies whether there is a need for a trial
Allows any protocol amendments to be seen
Publicly available resource for patients and doctors

Clinical trial registration services, some examples…

WHO International Clinical Trials Registry (ICTRP) **http://www.who.int/ictrp/en/**
US NIH Clinical Trials **http://www.clinicaltrials.gov**
Australia and New Zealand's (ANZCTR) **http://www.anzctr.org.au**
Brazilian Clinical Trials Registry (ReBec) **http://www.ensaiosclinicos.gov.br**
Chinese Clinical Trial Registry (ChiCTR) **http://www.chictr.org**
Clinical Research Information Service (CRiS), Republic of Korea **http://cris.cdc.go.kr**
Clinical Trials Registry - India (CTRI) **http://ctri.nic.in**
Cuban Public Registry of Clinical Trials(RPCEC) **http://registroclinico.sld.cu**
EU Clinical Trials Register (EU-CTR) **https://www.clinicaltrialsregister.eu/**
German Clinical Trials Register (DRKS) **http://www.drks.de**
Iranian Registry of Clinical Trials (IRCT) **http://www.irct.ir/**
Japan's UMIN-CTR **http://umin.ac.jp**
The Netherlands National Trial Register **http://www.trialregister.nl**
The International ISRCTN **http://isrctn.org/**
Pan African Clinical Trial Registry (PACTR) **http://www.pactr.org/**
Sri Lanka Clinical Trials Registry (SLCTR) **http://www.slctr.lk/**

Clinical trial registration: why important?



Distribution of pharmaceutical preclinical and clinical trials in 2016, by disease
WHO Technical Report: Pricing of cancer medicines and its impacts, 2019

Research in Context panel

Research in context

Evidence before this study

To identify other studies of inhibitors of PD-1 or PD-L1 in advanced cancers, including melanoma, we did a detailed search of PubMed and congress abstracts from the annual meetings of the American Society of Clinical Oncology, European Society of Medical Oncology/European Cancer Congress, and Society for Melanoma Research, between Jan 1, 2010 and Jan 13, 2015. We used the search terms "PD-1", "PD-L1", "nivolumab", "MK-3475", "pembrolizumab", "lambrolizumab", "MPDL3280A", and "MEDI4736". Our search identified several non-randomised, non-controlled phase 1/2 studies with promising levels of antitumour response for PD-1 and PD-L1 inhibitors in patients with advanced solid tumours, including melanoma. Although these data suggest activity for PD-1 inhibition in patients with melanoma that have progressed after ipilimumab and BRAF inhibitors, the sample sizes were too small to allow firm conclusions to be drawn on the efficacy and safety of PD-1 inhibition. Our review identified only one randomised, controlled, phase 3 study comparing an anti-PD-1 drug (nivolumab) with dacarbazine, but this study was done in treatment-naive patients who had *BRAF* wild-type tumours.

Added value of this study

For the patient population investigated in this study, treatment options are very restricted, and no prospective, randomised, controlled trial comparing an anti-PD-1 drug with any approved treatment has been done. Our data show that nivolumab led to clinically meaningful improvements in the proportion of patients achieving an objective response and provided a manageable safety profile when compared with chemotherapy.

Implications of all the available evidence

Nivolumab can now be deemed a new treatment option for patients that have progressed after ipilimumab, or a BRAF inhibitor and ipilimumab if their melanoma is $BRAF^{V600}$-mutated. These data resulted in the accelerated approval of nivolumab by the US Food and Drug Administration for this indication in December, 2014.

Search strategy for Reviews

Search strategy and selection criteria

We searched PubMed for early (phase 1 and 2) and randomised controlled (phase 3) clinical trials in advanced melanoma, published in English after 2000, with the terms "melanoma" and "treatment". These studies were reviewed for therapeutic approach, novelty, and clinical outcomes. We also searched PubMed with the terms "melanoma", "melanoma subtypes", "melanoma and BRAF V600E", "melanoma and KIT", "melanoma and bio-chemotherapy", "melanoma and CTLA-4", and "melanoma and survival". Relevant articles published after 1990 were selected as historical references and as a source of preclinical data to form the scientific rationale for current trial design in metastatic melanoma. Because of the novelty of the topic presented in this Review, several trials are ongoing; we therefore, searched for these clinical trials on the clinicaltrials.gov database and looked for "advanced melanoma" or "metastatic melanoma", or for specific novel agents being investigated.

Conflicts of interest and disclosure

A conflict of interest exists when an author or the author's institution has financial or personal relationships with other people or organisations that inappropriately influence (bias) his or her actions

A conflict of interest can undermine the credibility of the journal, the authors, and of the science

Financial interests include employment, consultancies, stock ownership, honoraria, and paid expert testimony

Conflicts can occur for other reasons, such as personal relationships, academic competition, and intellectual passion

ICMJE common disclosure form: www.icmje.org/coi_disclosure.pdf

For research articles: need full declaration. **For reviews:** might prevent submission

Role of the funding source

All sources of funding should be declared

Authors must describe the role of any study sponsor(s) in study design; in the collection, analysis, and interpretation of data; in the writing of the report; and in the decision to submit the paper for publication

The corresponding author should confirm whether he or she had full access to all the data in the study and had final responsibility for the decision to submit for publication

Role of medical writer or editor

If a medical writer or editor was involved, the name and information about funding of this person should be disclosed

Signed statements from any medical writers or editors declaring that they have given permission to be named as an author, as a contributor, or in the Acknowledgments section is important

What editors look for: plagiarism

Plagiarism is becoming an increasingly prominent problem
Editors expect all authors to submit original work and not be intellectually lazy
Plagiarism covers the copying of others work, duplicate publication, and 'text recycling'

The Lancet's journals have been routinely checking reviews, opinions, and comments for plagiarism since 2010 using specialist software
Offenders can be reported to their institution

Institutions are taking allegations of plagiarism very seriously akin to professional misconduct

The cover letter: important or not?

Be brief
Do not repeat abstract
Highlight the unique aspects of your paper *vs* current practice
Highlight why chosen journal is the best readership for your paper
Highlight upcoming events, or government or regulator decisions
Mention any people who would be inappropriate referees and why

Thank you for your attention—any questions?