

A tribute to Doug Altman

Jamie Kirkham, Senior Lecturer of Biostatistics, University of Liverpool
COMET VII Meeting, Amsterdam, The Netherlands
November 2018

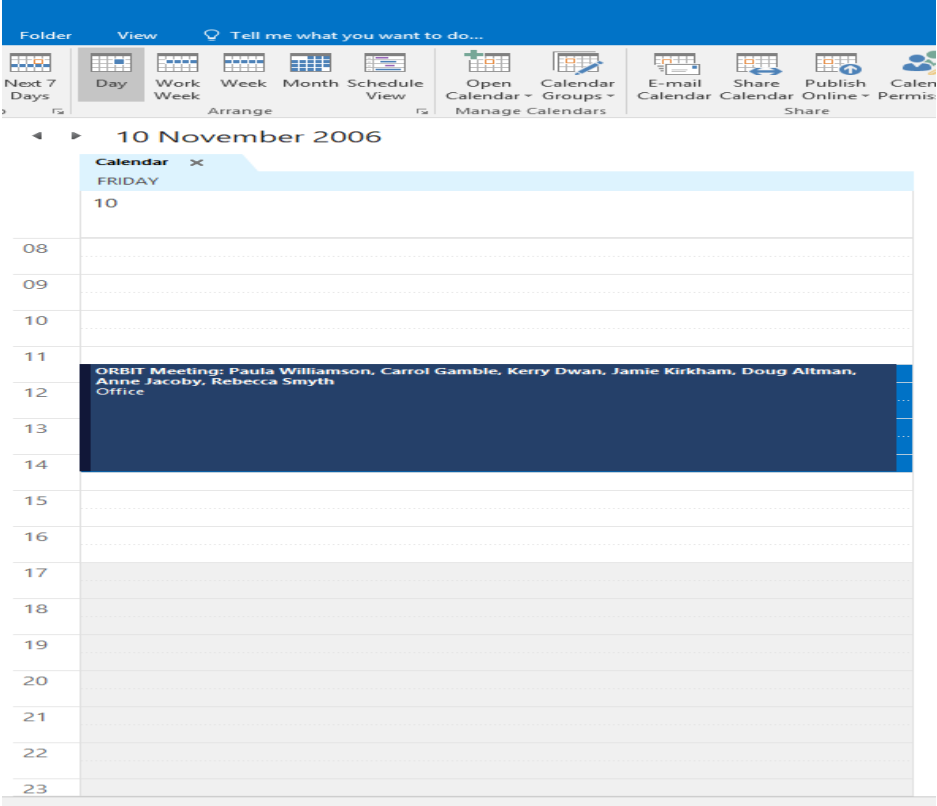
Acknowledgments

- COMET management group for inviting me
- Jon Deeks / Steven Evans for providing *some* of the slides, photos and comments
- Lots of other people for (mainly unpublished) comments



> 1600 co-authors

Meeting Doug for the first time...



Empirical Evidence for Selective Reporting of Outcomes in Randomized Trials

Comparison of Protocols to Published Articles

An-Wen Chan, MD, DPhil

Asbjørn Hróbjartsson, MD, PhD

Mette T. Haahr, BSc

Peter C. Gøtzsche, MD, DMedSci

Douglas G. Altman, DSc

SELECTIVE PUBLICATION OF STUDIES with statistically significant results has received widespread recognition.¹ In contrast, selective reporting of favorable outcomes within published studies has not undergone comparable empirical investigation. The existence of outcome reporting bias has been widely suspected for years,²⁻¹² but direct evidence is limited to assessments that have

Context Selective reporting of outcomes within published studies based on the nature or direction of their results has been widely suspected, but direct evidence of such bias is currently limited to case reports.

Objective To study empirically the extent and nature of outcome reporting bias in a cohort of randomized trials.

Design Cohort study using protocols and published reports of randomized trials approved by the Scientific-Ethical Committees for Copenhagen and Frederiksberg, Denmark, in 1994-1995. The number and characteristics of reported and unreported trial outcomes were recorded from protocols, journal articles, and a survey of trialists. An outcome was considered incompletely reported if insufficient data were presented in the published articles for meta-analysis. Odds ratios relating the completeness of outcome reporting to statistical significance were calculated for each trial and then pooled to provide an overall estimate of bias. Protocols and published articles were also compared to identify discrepancies in primary outcomes.

Main Outcome Measures Completeness of reporting of efficacy and harm outcomes and of statistically significant vs nonsignificant outcomes; consistency between primary outcomes defined in the most recent protocols and those defined in published

Investigation of within-study selective reporting in clinical research: follow-up of applications submitted to a local research ethics committee

S. Hahn PhD¹, P. R. Williamson PhD² and J. L. Hutton PhD³

¹Medical and Pharmaceutical Statistics Research Unit, University of Reading, Reading, UK

²Division of Statistics and Operational Research, Department of Mathematical Sciences, University of Liverpool, Liverpool, UK

³Department of Statistics, University of Warwick, Coventry, UK

Correspondence

Seokyoung Hahn
Department of Health Sciences
Alcuin College
The University of York
Heslington
York YO10 5DD
UK
E-mail: SH38@York.ac.uk

Keywords: meta-analysis, publication bias, research ethics committee, within-study selective reporting.

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Abstract

Rationale, aims and objectives Within-study selective reporting is widely believed to exist, although to date there have been no empirical studies to assess the extent of the problem in clinical research. The present study aimed to examine this process. **Methods** We undertook a pilot study, involving a single local research ethics committee (LREC), in which we compared the outcomes, analysis and sample size proposed in the original approved study protocol with the results presented in the subsequent study report. **Results** We received 41 (73%) replies from lead researchers of 56 projects, which were a complete cohort of clinical research applications approved in a particular time period by the LREC. Fifteen of these projects, which were completed and published at the time of our study, were further investigated. Only six (40%) stated which outcome variables were of primary interest and four (67%) of these showed consistency in the reports. Eight (53%) of the 15 studies mentioned an analysis plan. However, seven (88%) of these eight studies did not follow their prescribed analysis plan: the analysis of outcome variables or associations between certain variables were found to be missing from the report. **Conclusions** Our pilot study has shown that

“As a mentee, I always appreciated Doug's commitment to promoting the success of his students. I valued how **he opened doors for me while also giving me the room** to learn through the process of working independently.

I will always remember his wisdom, kindness, and clarity of thought, as well as his office full of papers stacked high (and his incredible ability to find a specific older paper buried within one of many piles)! ”

- An-Wen Chan



Doug's mission to improve medical research

- Statistics in medical journals
- Educational writing
- Interpretation of findings
- Reporting guidelines
- Meta-analysis and Cochrane
- Meta-epidemiology and Risk of bias



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Outcome reporting bias in trials: a methodological approach for assessment and adjustment in systematic reviews

Jamie J Kirkham,¹ Douglas G Altman,² An-Wen Chan,³ Carrol Gamble,¹ Kerry M Dwan,⁴ Paula R Williamson¹

¹MRC North West Hub for Trials Methodology Research, Department of Biostatistics, University of Liverpool, Liverpool L69 3GL, UK

²Centre for Statistics in Medicine, Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, Oxford, UK

³Department of Medicine, Women's College Research Institute, Women's College Hospital, University of Toronto, Toronto, ON, Canada

⁴Cochrane Editorial Unit, London, UK

Correspondence to: J Kirkham jjk@liv.ac.uk

Additional material is published online only. To view please visit the journal online.

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Systematic reviews of clinical trials aim to include all relevant studies conducted on a particular topic and to provide an unbiased summary of their results, producing the best evidence about the benefits and harms of medical treatments. Relevant studies, however, may not provide the results for all measured outcomes or may selectively report only some of the analyses undertaken, leading to unnecessary waste in the production and reporting of research, and potentially biasing the conclusions to systematic reviews. In this article, Kirkham and colleagues provide a methodological approach, with an example of how to identify missing outcome data and how to assess and adjust for outcome reporting bias in systematic reviews.

the results of a subset of the original variables recorded for inclusion in a publication.”²

Empirical research provides strong evidence that outcomes that are statistically significant have higher odds of being fully reported than non-significant outcomes (odds ratios ranging from 2.2 to 4.7).³⁻⁶ In the ORBIT (Outcome Reporting Bias In Trials) study, outcome reporting bias was suspected in at least one trial in more than a third (96/283; 34%) of Cochrane systematic reviews.⁵ In the follow-up study that looked at the same problem in a review of harm outcomes, review primary harm outcome data were missing from at least one eligible study in over 75% (252/322) of systematic reviews.⁶

The aim of this article is to show, with an example, how systematic reviewers can minimise the amount of missing data in reviews of healthcare interventions, and use ORBIT methods to detect and classify the suspicion of outcome reporting bias in benefits and harms reported in included studies. The paper also provides details of a statistical approach to assess the robustness of meta-analysis conclusions on this potential source of bias that non-methodologists can implement on a web based platform.

Selecting the most appropriate review outcomes

One way to streamline the process of systematic reviews and to help reduce outcome reporting bias is



Doug's contribution to COMET...

Cochrane Database of Systematic Reviews

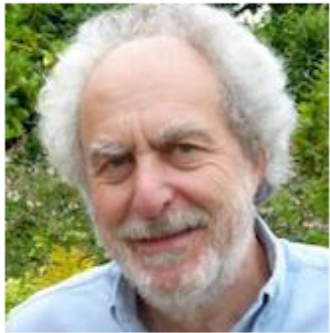
Doug Altman's legacy to Cochrane and evidence synthesis

Editorial | version published: 14 September 2018



[Jonathan J Deeks](#) | [Sally Hopewell](#) | [David Moher](#) | [Julian PT Higgins](#) | [Karel GM Moons](#) | [Jackie Chandler](#) | [Gerd Antes](#)

[View authors' declarations of interest](#)



It is hard to find an area of medicine or health research where the initiatives Doug Altman instigated and championed have not had an influence. Doug was a man on several missions: advocating statistical peer review to reduce statistical errors in medical journals; improving doctors' and health researchers' understanding of statistics and research design through thoughtful teaching; writing accessible and well-used statistical notes; producing a major medical statistics textbook; advocating a focus on estimating effects and confidence intervals rather than hypothesis testing; and providing numerous templates and guidelines to educate journals and researchers as to how they should

report their studies.[\[1, 2, 3, 4, 5, 6\]](#) Doug was one of the leaders of the COMET Initiative, promoting the development of core outcome sets to be measured and reported in all randomized trials of a specific condition, making it easier for the results of trials to be compared, contrasted, and combined as appropriate.[\[7\]](#) He also pushed for the development of reviews for prognostic research. His dedication to his work continued until a few days before he died.



(Some of) Doug's contributions to COMET...

Core Outcome Set-STANDARDISED Protocol Items: The COS-STAP Statement

Jamie J Kirkham¹, Sarah Gorst¹, Douglas G Altman², Jane M Blazeby³, Mike Clarke⁴, Sean Tunis⁵, Paula R Williamson^{1*} for the COS-STAP Group

¹MRC North West Hub for Trials Methodology Research, Department of Biostatistics, University of Liverpool, Liverpool, United Kingdom

²Centre for Statistics in Medicine, Nuffield Department of Orthopaedics, Rheumatology & Musculoskeletal Sciences, University of Oxford, United Kingdom

³MRC CoNDuCT II Hub for Trials Methodology Research, Population Health Sciences, University of Bristol, Bristol, United Kingdom

⁴Northern Ireland Hub for Trials Methodology Research, Centre for Public Health, Queen's University Belfast, Belfast, United Kingdom

⁵Center for Medical Technology Policy, Baltimore, USA

*Corresponding Author:

Professor Paula Williamson

Department of Biostatistics
University of Liverpool
Block F Waterhouse Building,
1-5 Brownlow Street, Liverpool,
L69 3GL

Email: prw@liv.ac.uk
Tel: +44 (0) 151 794 9758



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Citation: Kirkham JJ, Gorst S, Altman DG, Blazeby JM, Clarke M, Devane D, et al. (2016) Core Outcome Set-STANDards for Reporting: The COS-STAR Statement. *PLoS Med* 13(10): e1002148. doi:10.1371/journal.pmed.1002148

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Competing Interests: I have read the journal's policy and have the following conflicts: DGA, JMB, MC, EG, PRW, and ST are members of the COMET Management Group. DM is a member of the Editorial Board of *PLoS Medicine*. DD, SG, JJK, JS, and PT declare no competing interests.

Abbreviations: COMET, Core Outcome Measures in Effectiveness Trials; COS, core outcome sets; COS-STAR, Core Outcome Set-STANDards for Reporting; CROWN, CoRe Outcomes in Women's health; E+E, Explanation and Elaboration; EQUATOR, Enhancing the QUALity and

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Competing interests: I have read the journal's policy and have the following conflicts: DGA, JMB, MC, ST, and PRW are members of the COMET Management Group. KD and JJK declare no competing interests.

Abbreviations: COMET, Core Outcome Measures in Effectiveness Trials; COS, core outcome set(s); COS-STAD, Core Outcome Set-STANDards for Development; COS-STAR, Core Outcome Set-STANDards for Reporting; PoPPIE, Public and



Doug with long-time collaborators, David Moher and Ken Schulz

“Doug was always fun to be with and he did have an infectious laugh.”

“He possessed qualities that brought people together”

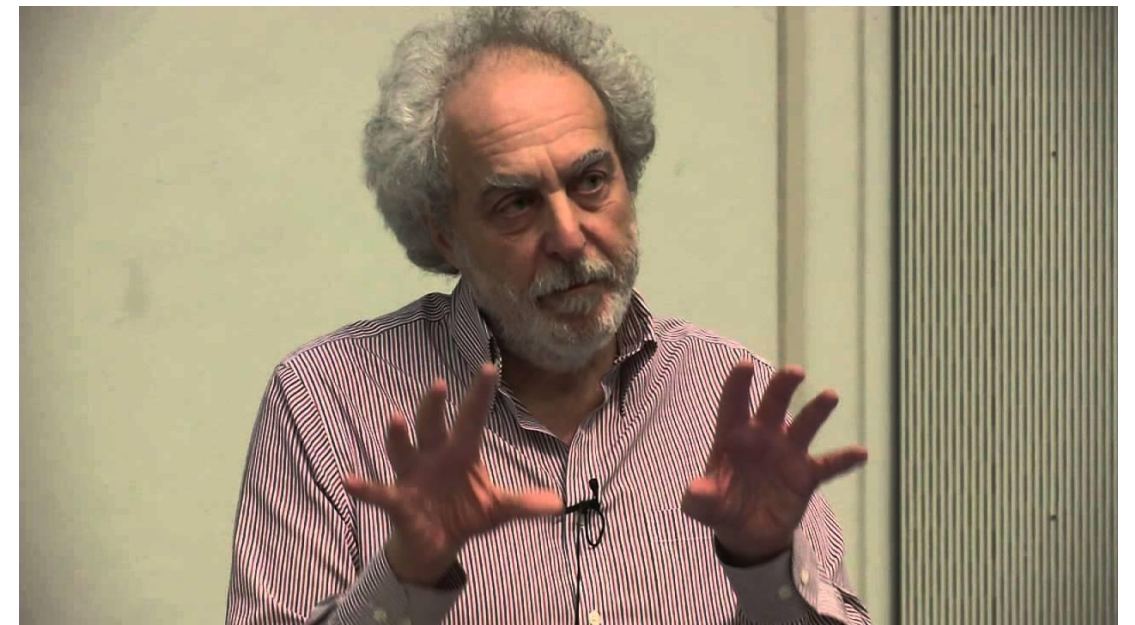
Reporting guidelines

- Ken Schulz

(Some of) Doug's Awards...

... if anybody in the audience never heard of Doug, they were likely aliens from another planet! That is how influential he was (and still is). Doug was modest about his out of the world achievements

- David Moher



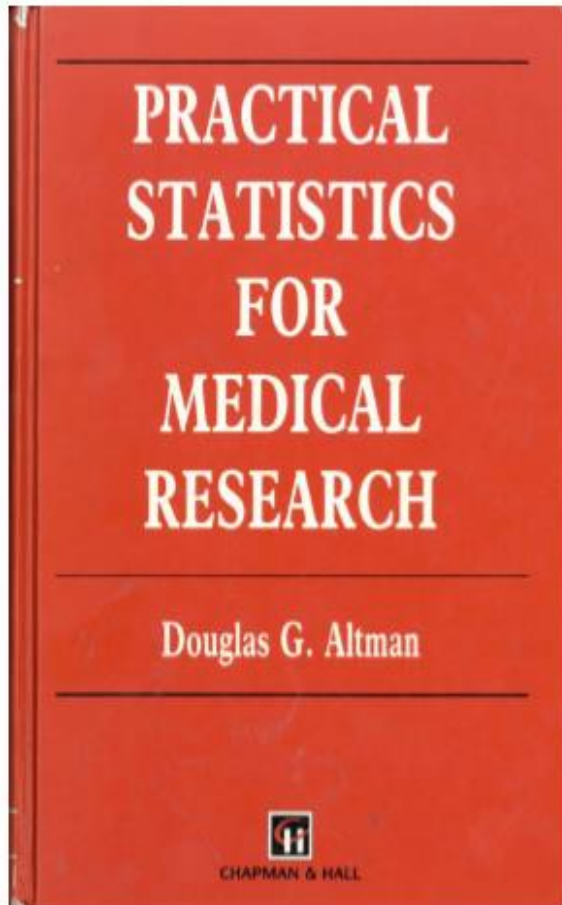
Royal Statistical Society Bradford Hill Medal – 1997



Honorary Doctorate from the University of Utrecht –2015



BMJ Lifetime Achievement Award – 2015



“The thing I’m most proud of achieving is writing a textbook. It is extremely easy to start one, but extremely difficult to finish.

I read a lot and I learned a lot during the process. That was twenty-five years ago, but people are still buying it, which is really remarkable.

...you want people to find it helpful and the positive feedback I have received about it has been very gratifying.”

Interview with Methods in Research on Research (MiRoR) Fellows (2018)

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by Douglas G. Altman (Author)

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“An editor's life is all about decisions. So many of the difficult decisions I have had to make over the years have been made easier - even turned from stressful to delightful - by knowing we had Doug to guide us.”

- Fiona Godlee (BMJ EIC)



Author	Year	Title	Journal
J. M. Altman, D. G.	1977	ENTERIC DISEASE IN SAN FRANCISCO	Lancet
J. M. Altman, D. G.	1980	STATISTICS AND ETHICS IN MEDICAL RESEARCH 7. INTERPRETING RESULTS	British Medical J.
J. M. Altman, D. G.	1981	STATISTICS AND ETHICS IN MEDICAL RESEARCH 8. IMPROVING THE QUALITY	British Medical J.
J. M. Altman, D. G., J. M.	1983	MEASUREMENT IN MEDICINE - THE ANALYSIS OF METHOD COMPARISON	Journal of the...
J. M. Altman, D. G., J. M.	1986	COMPARISON OF METHODS OF MEASURING BLOOD-PRESSURE	Journal of Epid...
J. M. Altman, D. G.	1986	REGRESSION ANALYSIS	Lancet
J. M. Altman, D. G.	1986	STATISTICAL METHODS FOR ASSESSING AGREEMENT BETWEEN TWO MET...	Lancet
J. M. Altman, D. G., J. M.	1987	COMPARING METHODS OF MEASUREMENT	Applied Statist...
J. M. Altman, D. G.	1987	CHEAT DOCTOR: A GRIM TALE OF MEDICAL STATISTICS TEXTBOOKS	British Medical ...
J. M. Altman, D. G.	1988	MISLEADING STATISTICS - ERRORS IN TEXTBOOKS, SOFTWARE AND MAN...	International J...
J. M. Altman, D. G.	1990	A NOTE ON THE USE OF THE INTRACLASS CORRELATION COEFFICIENT IN...	Computers in B...
J. M. Altman, D. G., R.	1990	STATISTICS IN MEDICAL JOURNALS	Journal of the...
Obrien, E., Perrie, J., Little...	1990	THE BRITISH HYPERTENSION SOCIETY PROTOCOL FOR THE EVALUATION...	Journal of Hyp...
J. M. Altman, D. G.	1991	STATISTICS IN MEDICAL JOURNALS - DEVELOPMENTS IN THE 1980S	Statistics in Me...
J. M. Altman, D. G., J. M.	1991	IMPROVING DOCTORS UNDERSTANDING OF STATISTICS	Journal of the...
Ponick, S., Altman, D., Arin...	1991	STATISTICS AND STATISTICIANS IN DRUG REGULATION IN THE UNITED K...	Journal of the...
J. M. Altman, D. G., J. M.	1992	FETAL GROWTH AND RATIO OF PLACENTAL WEIGHT TO BIRTH-WEIGHT	British Medical ...
J. M. Altman, D. G.	1992	COMPARING METHODS OF CLINICAL MEASUREMENT - A CITATION CLASS...	Current Conte...
J. M. Altman, D. G.	1993	INFORMED CONSENT	British Medical ...
Obrien, E., Perrie, J., Little...	1993	AN OUTLINE OF THE REVISED BRITISH HYPERTENSION SOCIETY PROTOC...	Journal of Hyp...
J. M. Altman, D. G.	1994	THE SCANDAL OF POOR MEDICAL RESEARCH	British Medical ...
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J. M. Altman, D. G.	1995	COMPARING METHODS OF MEASUREMENT - WHY PLOTTING DIFFERENC...	Lancet
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Obrien, E., Fairfield, P., Blau...	1995	VALIDATION OF BLOOD-PRESSURE MEASURING DEVICES	Journal of Clinic...
J. M. Altman, D. G., J. M.	1996	Statistics notes - Detecting skewness from summary information	British Medical ...
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J. M. Altman, D. G., Matthews, J...	1996	Statistics notes 24. Heterogeneity of effects	British Medical ...
J. M. Altman, D. G.	1996	Statistics notes - Measurement error proportional to the mean (vol 313, pg...	British Medical ...
J. M. Altman, D. G.	1996	Statistics notes 21. Measurement error (vol 312, pg 1654, 1995)	British Medical ...
J. M. Altman, D. G.	1996	Statistics notes - Measurement error proportional to the mean 23	British Medical ...
J. M. Altman, D. G.	1996	Measurement error and correlation coefficients	British Medical ...
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Obrien, E. T., Ong, J., Blau...	1996	Testis conservation studies in germ cell cancer justified by improved prima...	British Journal ...
Sharp, S. J., Thompson, S. G...	1996	The relation between treatment benefit and underlying risk in meta-analy...	British Medical ...
J. M. Altman, D. G., J. M.	1997	Statistics notes - Unity of analysis	British Medical ...
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Vickers, J. J., Altman, D. G.	2001	Statistics notes - Analysing controlled trials with baseline and follow up me...	British Medical ...
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McKibbin, A., Strauss, S. E...	2003	Analysis and reporting of factorial trials - A systematic review	Jama Journal o...
Altman, D. G., J. M.	2004	Confidence intervals (bivariate analysis of evidence)	British Medical ...
J. M. Altman, D. G.	2004	The logrank test (vol 326, pg 1073, 2004)	British Medical ...
J. M. Altman, D. G.	2004	The logrank test	British Medical ...
Dewick, L. J., Altman, D. G.	2004	Statistics notes - Diagnostic tests 4. Likelihood ratios	British Medical ...
J. M. Altman, D. G., J. M.	2005	Statistics notes - Standard deviations and standard errors	British Medical ...
J. M. Altman, D. G., J. M.	2005	Treatment allocation by minimisation	British Medical ...



“One behavior not too many people knew – he was a huge list fanatic e.g. he had a list of every peer review he’s ever done – thousands!”

- David Moher

“Bad research is not good for patients”

Doug’s research mattered to him because improving the quality of medical research better informed the care of patients.

We have no doubt that Doug’s many outstanding contributions have left the world a better place for patients

Jeff Aronson- BMJ Blog June 8th 2018

... But the best description of all, in my view, was the suggestion that he had “geniousness”. Now this word is not to be found in any dictionary that I know of, although it deserves to be in them all. So what does it mean? Well it’s clearly a portmanteau word.”

Genius + generousness

Twitter: A “funomenon” - “fun” + “phenomenon”



Doug we salute you!