

Title: Data Sharing

References:

- 1.- Alfonso F, Ambrosio G, Pinto FJ, Van der Wall EE, Kondili A, Nibouche D, Adamyan K, Huber K, Ector H, Masic I, Tarnovska R, Ivanusa M, Staněk V, Videbaek J, Hamed M, Laucevicius A, Mustonen P, Artigou JY, Cohen A, Rogava M, Böhm M, Fleck E, Heusch G, Klawki R, Vardas P, Stefanadis C, Tenczer J, Chiariello M, Elias J, Benjelloun H, Rødevand O, Kułakowski P, Apetrei E, Lusov VA, Oganov RG, Obradovic V, Kamensky G, Kenda MF, Höglund C, Lüscher TF, Lerch R, Jokhadar M, Haouala H, Sansoy V, Shumakov V, Timmis A. [European National Society cardiovascular journals. Background, rationale and mission statement of the "Editors' Club"](#). Rev Esp Cardiol. 2008 Jun;61(6):644-50.
- 2.- [Alfonso F, Ambrosio G, Pinto FJ, Ector H, Vardas P, Kulakowski P, Timmis A; Editors' Network ESC Task Force](#). European Society of Cardiology national cardiovascular journals: the 'Editors' Network'. [Eur Heart J](#). 2010 Jan;31(1):26-8.
- 3.- Mills P, Timmis A, Huber K, Ector H, Lancellotti P, Masic I, Ivanusa M, Antoniades L, Aschermann M, Laucevicius A, Mustonen P, Artigou JY, Vardas P, Stefanadis C, Chiarello M, Bolognese L, Ambrosio G, van der Wall EE, Kułakowski P, Pinto FJ, Apetrei E, Oganov RG, Kamensky G, Lüscher TF, Lerch R, Haouala H, Sansoy V, Shumakov V, Tajer CD, Lau CP, Márquez M, Krittayaphong R, Arai K, Alfonso F. [The role of European national journals in education](#). Heart. 2009 Dec;95(24):e3.
- 4.- Alfonso F. [The Editors' Network of the European Society of Cardiology](#). Eur Heart J. 2011 Apr;32(8):919-21.
- 5.- International Committee of Medical Journals Editors. Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals Updated December 2015 Available: <http://www.icmje.org>.
- 6.- Council of Science Editors. White Paper on Publication Ethics. CSE's White Paper on Promoting Integrity in Scientific Journal Publications, 2012 Update Available: <http://www.CouncilScienceEditors.org>.
- 7.- World Association of Medical Editors. WAME Professionalism Code of Conduct The new WAME Professionalism Code of Conduct for medical journal editors. Available: <http://www.wame.org>.
- 8.- Committee On Publication Ethics. COPE. Code of Conduct and Best Practice Guidelines for Journal Editors. Available: <http://publicationethics.org/resources/guidelines>.
9. De Angelis CD, Drazen JM, Frizelle FA, Haug C, Hoey J, Horton R, Kotzin S, Laine C, Marusic A, Overbeke AJ, Schroeder TV, Sox HC, Van Der Weyden MB; International Committee of Medical Journal Editors. [Is this clinical trial fully registered?--A statement from the International Committee of Medical Journal Editors](#). N Engl J Med. 2005 Jun 9;352(23):2436-8.
- 10.- Alfonso F, Segovia J, Heras M, Bermejo J. [Publication of clinical trials in scientific journals: Editorial issues](#). Rev Esp Cardiol. 2006 Nov;59(11):1206-14.

- 11.- Drazen JM, Van der Weyden MB, Sahni P, Rosenberg J, Marusic A, Laine C, Kotzin S, Horton R, Hébert PC, Haug C, Godlee F, Frizelle FA, de Leeuw PW, DeAngelis CD. [Uniform format for disclosure of competing interests in ICMJE journals](#). N Engl J Med. 2009;361(19):1896-7.
12. Alfonso F, Timmis A, Pinto FJ, Ambrosio G, Ector H, Kulakowski P, Vardas P; Editors' Network European Society of Cardiology Task Force. [Conflict of interest policies and disclosure requirements among European Society of Cardiology National Cardiovascular Journals](#). Eur Heart J. 2012 Mar;33(5):587-94.
13. Davidoff F, DeAngelis CD, Drazen JM, Nicholls MG, Hoey J, Højgaard L, Horton R, Kotzin S, Nylenna M, Overbeke AJ, Sox HC, Van Der Weyden MB, Wilkes MS. [Sponsorship, authorship, and accountability](#). N Engl J Med. 2001 Sep 13;345(11):825-6;
14. Taichman DB, Backus J, Baethge C, Bauchner H, de Leeuw PW, Drazen JM, Fletcher J, Frizelle FA, Groves T, Haileamlak A, James A, Laine C, Peiperl L, Pinborg A, Sahni P, Wu S. [Sharing Clinical Trial Data--A Proposal from the International Committee of Medical Journal Editors](#). N Engl J Med. 2016 Jan 28;374(4):384-6.
15. Merson L, Gaye O, Guerin PJ. [Avoiding Data Dumpsters--Toward Equitable and Useful Data Sharing](#). N Engl J Med. 2016 Jun 23;374(25):2414-5.
16. Krumholz HM, Waldstreicher J. [The Yale Open Data Access \(YODA\) Project--A Mechanism for Data Sharing](#). N Engl J Med. 2016 Aug 4;375(5):403-5.
17. [Loder E, Groves T](#). The BMJ requires data sharing on request for all trials. [BMJ](#). 2015 May 7;350:h2373. doi: 10.1136/bmj.h2373.
18. Kavsak PA. The International Committee of Medical Journal Editors proposal for sharing clinical trial data and the possible implications for the peer review process. Ann Transl Med 2016;4(6):115.
19. Manamley N, Mallett S, Sydes MR, Hollis S, Scrimgeour A, Burger HU, Urban HJ. [Data sharing and the evolving role of statisticians](#). BMC Med Res Methodol. 2016 Jul 8;16 Suppl 1:75.
20. Institute of Medicine. Sharing clinical trial data: maximizing benefits, minimizing risk. Washington, DC: The National Academies Press; 2015.
21. Vallance P, Freeman A, Stewart M. [Data Sharing as Part of the Normal Scientific Process: A View from the Pharmaceutical Industry](#). PLoS Med. 2016 Jan 5;13(1):e1001936.
22. www.who.int/ictrp/results/WHO_Statement_results_reporting_clinical_trials.pdf?ua=1.
23. Modjarrad K, Moorthy VS, Millet P, Gsell P-S, Roth C, Kiény M-P. Developing global norms for sharing data and results during public health emergencies. PLoS Med 2015; 13(1):e1001935.
24. Coady SA, Wagner E. Sharing individual level data from observational studies and clinical trials: a perspective from NHLBI. Trials. 2013;14:201.

25. Geifman N, Bollyky J, Bhattacharya S, Butte AJ. [Opening clinical trial data: are the voluntary data-sharing portals enough?](#) BMC Med. 2015 Nov 11;13:280.
26. Van Tuyl S, Whitmire AL. [Water, Water, Everywhere: Defining and Assessing Data Sharing in Academia.](#) PLoS One. 2016 Feb 17;11(2):e0147942.
27. Sudlow R, Branson J, Friede T, Morgan D, Whately-Smith C. [EFSPI/PSI working group on data sharing: accessing and working with pharmaceutical clinical trial patient level datasets - a primer for academic researchers.](#) BMC Med Res Methodol. 2016 Jul 8;16 Suppl 1:73.
28. Drazen JM. [Data Sharing and the Journal.](#) N Engl J Med. 2016 May 2;374(19):e24. doi: 10.1056/NEJMe1601087.
29. Hopkins C, Sydes M, Murray G, et al. UK publicly funded Clinical Trials Units supported a controlled access approach to share individual participant data but highlighted concerns. J Clin Epidemiol 2016;70:17-25.
30. Lo B. Sharing clinical trial data: maximizing benefits, minimizing risk. JAMA. 2015;313(8):793-4.
31. Ross JS, Krumholz HM. [Open Access Platforms for Sharing Clinical Trial Data.](#) JAMA. 2016 Aug 9;316(6):666.
32. Academic Research Organization Consortium for Continuing Evaluation of Scientific Studies--Cardiovascular (ACCESS CV). [Sharing Data from Cardiovascular Clinical Trials--A Proposal.](#) N Engl J Med. 2016 Aug 4;375(5):407-9.
33. Manamley N, Mallett S, Sydes MR, Hollis S, Scrimgeour A, Burger HU, Urban HJ. [Data sharing and the evolving role of statisticians.](#) BMC Med Res Methodol. 2016 Jul 8;16 Suppl 1:75.
34. Fletcher C, Hollis S, Burger HU, Gerlinger C. [Statistical guidance for responsible data sharing: an overview.](#) BMC Med Res Methodol. 2016 Jul 8;16 Suppl 1:74.
35. Tucker K, Branson J, Dilleen M, Hollis S, Loughlin P, Nixon MJ, Williams Z. [Protecting patient privacy when sharing patient-level data from clinical trials.](#) BMC Med Res Methodol. 2016 Jul 8;16 Suppl 1:77.
36. International Consortium of Investigators for Fairness in Trial Data Sharing, Devereaux PJ, Guyatt G, Gerstein H, Connolly S, Yusuf S. [Toward Fairness in Data Sharing.](#) N Engl J Med. 2016 Aug 4;375(5):405-7.
37. Hayes R, Ayles H, Binka F, Cowan F, Kamali A, Kapiga S, Kleinschmidt I, Mayaud P, Patel V, Smith P, Weiss H. [Sharing clinical trial data.](#) Lancet. 2016 Jun 4;387(10035):2287.
38. Strom BL, Buyse M, Hughes J, Knoppers BM. Data sharing, year 1 — access to data from industry-sponsored clinical trials. N Engl J Med 2014; 371: 2052-4.

39. Navar AM, Pencina MJ, Rymer JA, Louzao DM, Peterson ED. Use of open access platforms for clinical trial data. *JAMA* 2016;315:1283-4.

40. Gonçalves LM, Seabra-Gomes R. Celebrating the 10th anniversary of the Portuguese Cardiology Data Collection Center: a reflexion on its past, present, and future]. *Rev Port Cardiol.* 2012 Dec;31(12):763-8.

41. Horton R. Offline: Data sharing why editors may have got it wrong. *Lancet* 2016;388:1143.