Retos de los Editores de Revistas Científicas

Dr. José G. Merino
US Clinical Research Editor, The BMJ

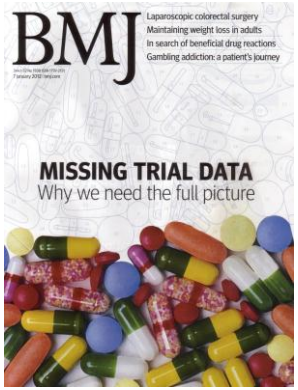
Retos Múltiples

- Línea editorial
- Relación con sociedades científicas
- Nueva tecnología para publicar
- Acceso abierto
- Fraude, plagio, mala conducta científica

Retos Múltiples

- Línea editorial
- Relación con sociedades científicas
- Nueva tecnología
- Acceso abierto
- Fraude, plagio, mala conducta científica
- **Transparencia**

“Las revistas científicas tienen la responsabilidad de usar cualquier poder que tengan para promover la transparencia en la labor científica.”




BMJ

BMJ 2012;345:e7304 doi: 10.1136/bmj.e7304 (Published 29 October 2012) Page 1 of 2

EDITORIALS

Clinical trial data for all drugs in current use

Must be made available for independent scrutiny

Fiona Godlee *editor in chief*

BMJ

BMJ 2012;345:e7332 doi: 10.1136/bmj.e7332 (Published 31 October 2012) Page 1 of 1

EDITOR'S CHOICE

Open data: seize the moment

Trevor Jackson *deputy editor, BMJ*

BMJ

BMJ 2012;344:d8158 doi: 10.1136/bmj.d8158 (Published 3 January 2012) Page 1 of 2

EDITORIALS

Missing clinical trial data

A threat to the integrity of evidence based medicine

Richard Lehman *senior research fellow*[1], Elizabeth Loder *clinical epidemiology editor*[2]

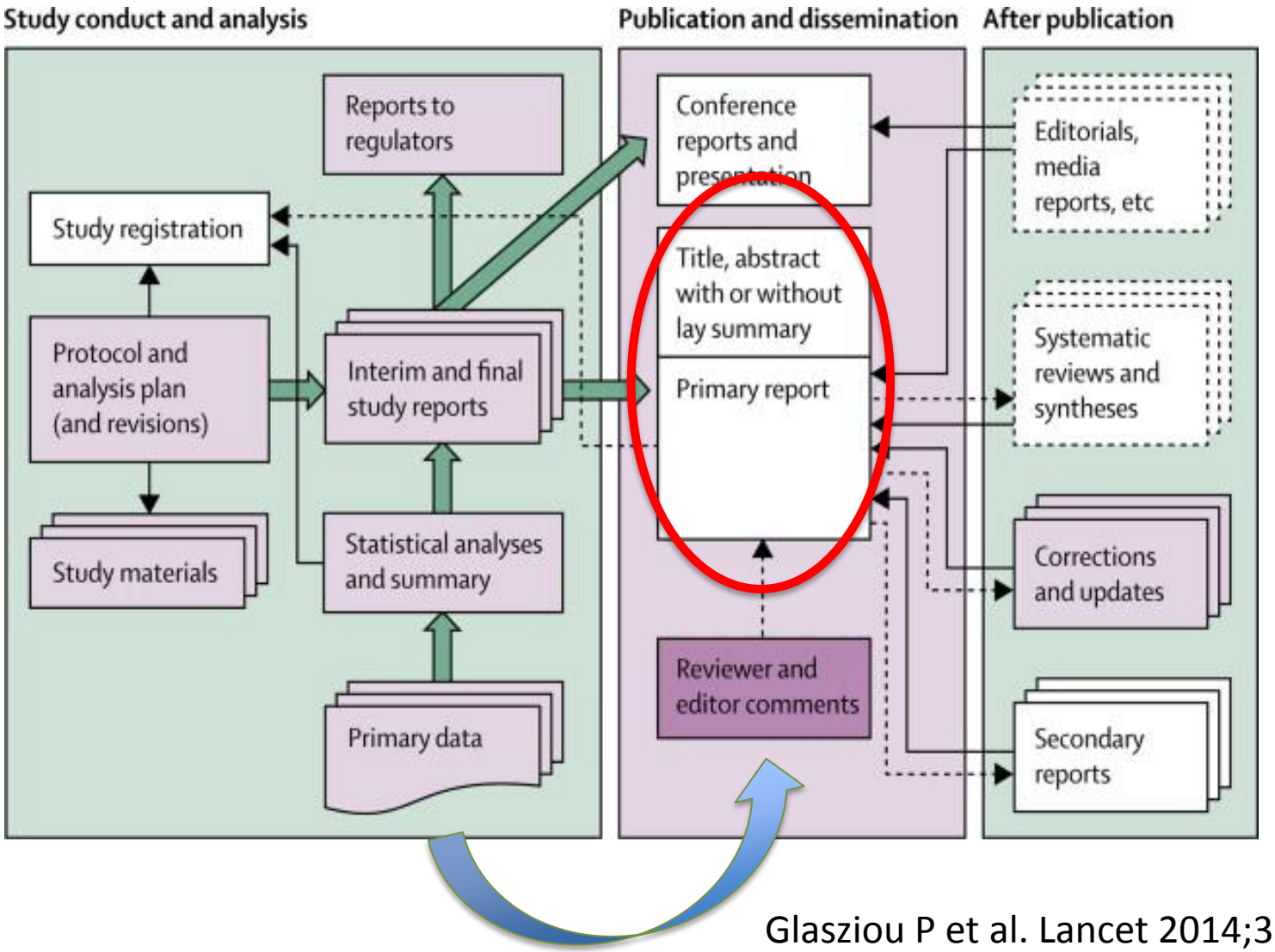
[1]Department of Primary Care, University of Oxford, Oxford OX1 2ET, UK; [2]BMJ, London WC1H 9JR, UK

Clinical medicine involves making decisions under uncertainty. Clinical research aims to reduce this uncertainty, usually by performing experiments on groups of people who consent to run the risks of such trials in the belief that the resulting

"Key stakeholders—including medical journal editors, legislators, and funding agencies—provide enforcement mechanisms that have greatly improved adherence to registration practices."

Godlee F, Groves T. *BMJ,* 2013

El Articulo es una Sinopsis

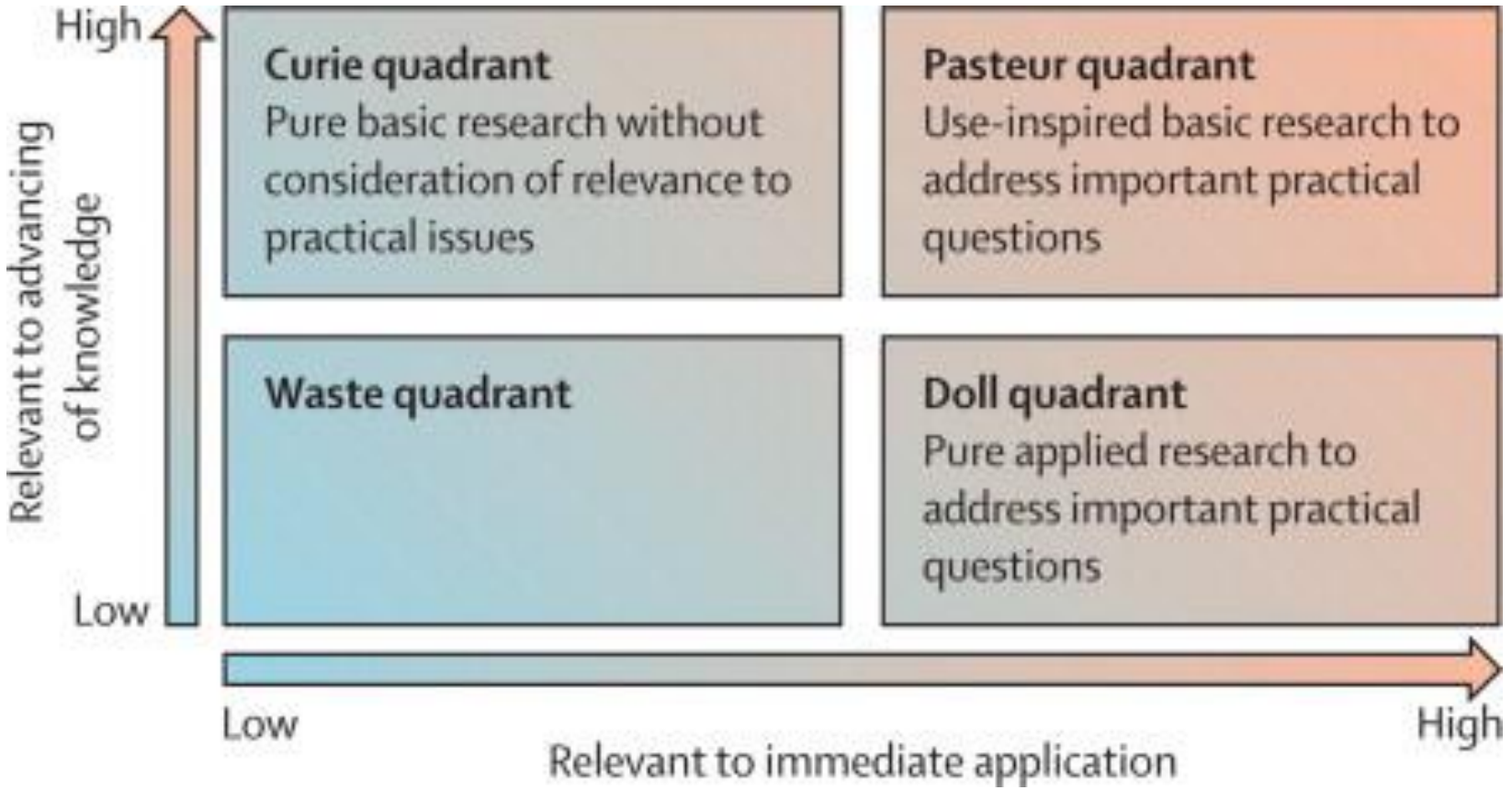


Glasziou P et al. Lancet 2014;383:267

Transparencia y Reproducibilidad

1. ¿Cual es la pregunta y por qué es importante?
2. ¿Qué hicieron?
3. ¿Qué encontraron?
4. ¿Qué quieren decir los resultados?
5. ¿Quién hizo el estudio?
6. ¿Quién pago el estudio?
7. ¿Cómo se tomaron las decisiones editoriales?
8. ¿Cómo pueden otros replicar el estudio?

Relevancia



Chalmers I et al. Lancet 2014;383:156

Métodos

	Number and selection of studies	Items absent in reports and proportion of studies that included items
Diagnostic studies[15] (STARD[16])	90 diagnostic accuracy studies of commercial tests for tuberculosis, malaria, and HIV reported 2004–06 and indexed on PubMed and Embase	STARD items that were reported in less than 25% of studies: methods for calculation and estimates of reproducibility (0%), adverse effects of the diagnostic tests (1%), estimates of diagnostic accuracy between subgroups (10%), distribution of severity of disease or other diagnoses (11%), number of eligible patients who did not participate in the study (14%), blinding of the test readers (16%), description of the team doing the test (17%), and management of indeterminate or outlier results (17%)
Animal studies[17] (ARRIVE[18])	271 reports of original research on live rats, mice, and non-human primates indexed on Medline and Embase between January, 1999, and March, 2005	Reporting of the hypothesis or objective, and the number and characteristics of the animals used (59%), sample size explained (0%), and reporting of exact numbers of animals in method and result section (46%)
Observational studies[19] (STROBE[20]; STREGA[21])	174 observational studies of interventions in five general medical and five epidemiological journals published between January, 2004, and April, 2007	For STROBE: details of selection (10%), and inclusion of confounders (51%)
Clinical prediction research[22] (REMARK[23] tumour markers prognosis; GRIPS[24] genetic risk prediction)	71 publications in six high-impact-factor general medical journals in 2008	Assessment of predictors and outcomes (blinding reported in 22% and 75%), sample size calculation reported (17%), missing data reported (62%), methods used for handling of missing data reported (46%), and reporting of adjusted (20%) and unadjusted (18%) results of the full model with all candidate predictors considered
Surveys[25]	117 studies from the top 15 high-impact-factor journals for health science, public health, general internal medicine, and medical informatics published between January, 2008, and February, 2009	Provision of the survey or core questions (35%), reporting of the psychometric properties of existing instrument (10%), clear description of development process or pretest methods (17%), description of sample representativeness (11%), and reporting of sample size calculation (6%)
Surveys[26]	Publication of 88 novel questionnaires from *Journal of the American Medical Association*, *New England Journal of Medicine*, and *The Lancet* from January, 2000, to May, 2003	Access to the questionnaire from the published report (8%), access after authors were contacted (54%)
Qualitative studies[27]	30 (19 reported) qualitative studies alongside randomised controlled trials of complex health-care intervention	Study context described (27%), sampling method described (37%), method of data collection described (40%), and method of analysis described (43%)

Table: Examples of inadequate reporting in studies other than randomised controlled trials and systematic reviews

BMJ

Glasziou P et al. Lancet 2014;383:267

Lineamientos Para Reportar Estudios

- CONSORT: Ensayos clínicos
- PRISMA: Revisiones sistemáticas y meta-análisis
- MOOSE: Meta- análisis
- STARDS: Diagnostico
- STROBE: Observacionales
- GRADE: Guías terapéuticas
- CHEERS: Evaluaciones económicas

CONSORT 2010 lista de comprobación de la información que hay que incluir al comunicar un ensayo clínico aleatorizado *

Sección/tema	Item nº	Ítem de la lista de comprobación	Informado en pagina nº
Título y resumen			
	1a	Identificado como un ensayo aleatorizado en el título	
	1b	Resumen estructurado del diseño, métodos, resultados y conclusiones del ensayo (para una orientación específica, véase "CONSORT for abstracts")	
Introducción			
Antecedentes y objetivos	2a	Antecedentes científicos y justificación	
	2b	Objetivos específicos o hipótesis	
Métodos			
Diseño del ensayo	3a	Descripción del diseño del ensayo (p. ej., paralelo, factorial), incluida la razón de asignación	
	3b	Cambios importantes en los métodos después de iniciar el ensayo (p. ej., criterios de selección) y su justificación	
Participantes	4a	Criterios de selección de los participantes	
	4b	Procedencia (centros e instituciones) en que se registraron los datos	
Intervenciones	5	Las intervenciones para cada grupo con detalles suficientes para permitir la replicación, incluidos cómo y cuándo se administraron realmente	
Resultados	6a	Especificación a priori de las variables respuesta (o desenlace) principal(es) y secundarias, incluidos cómo y cuándo se evaluaron	
	6b	Cualquier cambio en las variables respuesta tras el inicio del ensayo, junto con los motivos de la(s) modificacion(es)	
Tamaño muestral	7a	Cómo se determinó el tamaño muestral	
	7b	Si corresponde, explicar cualquier análisis intermedio y las reglas de interrupción	
Aleatorización:			
Generación de la secuenccia	8a	Método utilizado para generar la secuencia de asignación aleatoria	
	8b	Tipo de aleatorización; detalles de cualquier restricción (como bloques y tamaño de los bloques)	
Mecanismo de ocultación de la asignación	9	Mecanismo utilizado para implementar la secuencia de asignación aleatoria (como contenedores numerados de modo secuencial), describiendo los pasos realizados para ocultar la secuencia hasta que se asignaron las intervenciones	
Implementación	10	Quién generó la secuencia de asignación aleatoria, quién seleccionó a los participantes y quién asignó los participantes a las intervenciones	

CONSORT 2010 Diagrama de flujo

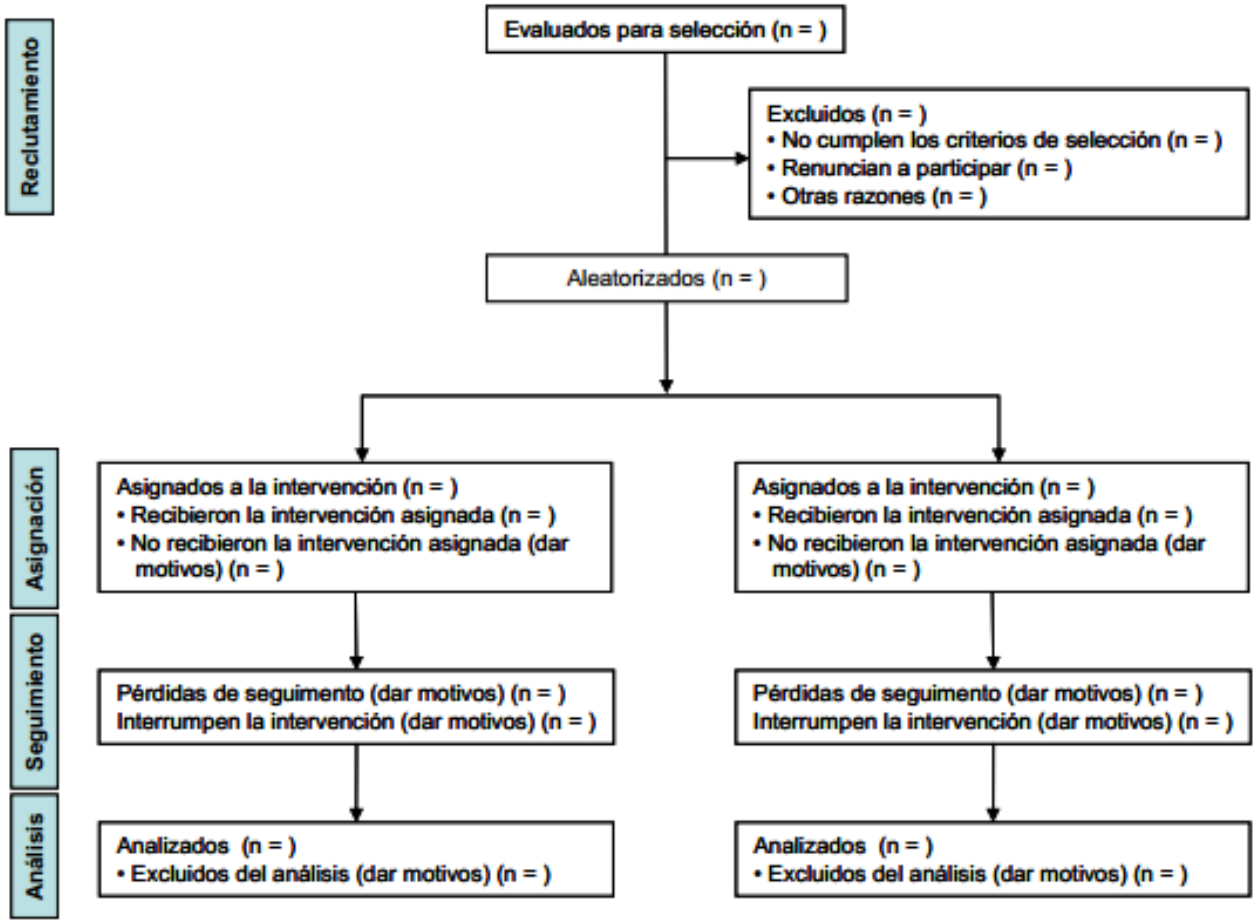


Diagrama de flujo del progreso a través de las fases de un ensayo clínico aleatorizado paralelo de dos grupos (esto es, reclutamiento, asignación de la intervención, seguimiento y análisis)

equator network

Enhancing the QUAlity and Transparency Of health Research

Visit the EQUATOR Spanish Website

The resource centre for good reporting of health research studies

Library for health research reporting

The Library contains a comprehensive searchable database of reporting guidelines and also links to other resources relevant to research reporting.

Search for reporting guidelines

Visit the library for more resources

Key reporting guidelines

CONSORT	Full Record	Checklist	Flow Diagram
STROBE	Full Record	Checklist	
PRISMA	Full Record	Checklist	Flow Diagram
STARD	Full Record	Checklist	Flow Diagram
COREQ	Full Record		
ENTREQ	Full Record		
SQUIRE	Full Record	Checklist	
CHEERS	Full Record	Checklist	
CARE	Full Record	Checklist	
SAMPL	Full Record		

Toolkits

The EQUATOR Network works to improve the reliability and value of medical research literature by promoting transparent and accurate reporting of research studies.

Our Toolkits support different user groups, including:

Authors
Information and resources for authors

Editors
Information and resources for editors and peer reviewers

Developers

EQUATOR highlights

4/12/2013 - Support transparent and accurate publication of health research

The EQUATOR Network has recently received numerous endorsements recognising its role in working to improve the reliability and value of medical research literature by promoting transparent and accurate reporting of research studies. We encourage more organisations to express their commitment to accurate and transparent reporting Read More

23/10/2013 - Updated Declaration of Helsinki

The World Medical Association just released an update of the "Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects". Paragraphs 35 and 36 on RESEARCH REGISTRATION AND PUBLICATION AND DISSEMINATION OF RESULTS state: 35. Every research study involving ... Read More

10/10/2013 - Declaration of transparency

A BMJ editorial published today proposes that authors of research papers are asked to sign a declaration that their paper is not misleading. The scientific community and the public at large deserve an accurate

News

New guideline for better description of interventions
7/03/2014

Reporting guidelines in veterinary journals
5/03/2014

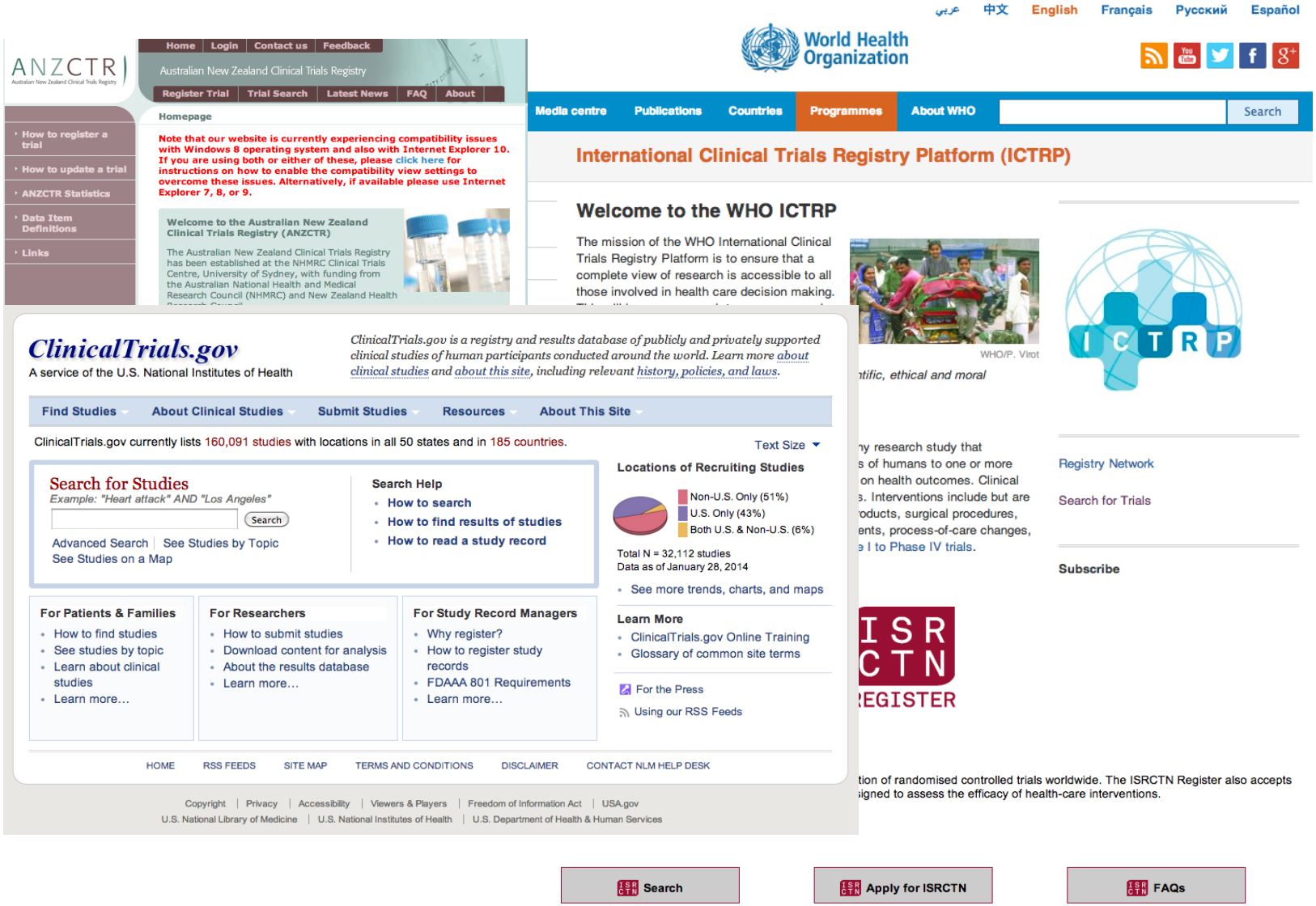
Threaded publications update
14/02/2014

VACANCY: EQUATOR Network is seeking a new co-ordinator
12/02/2014

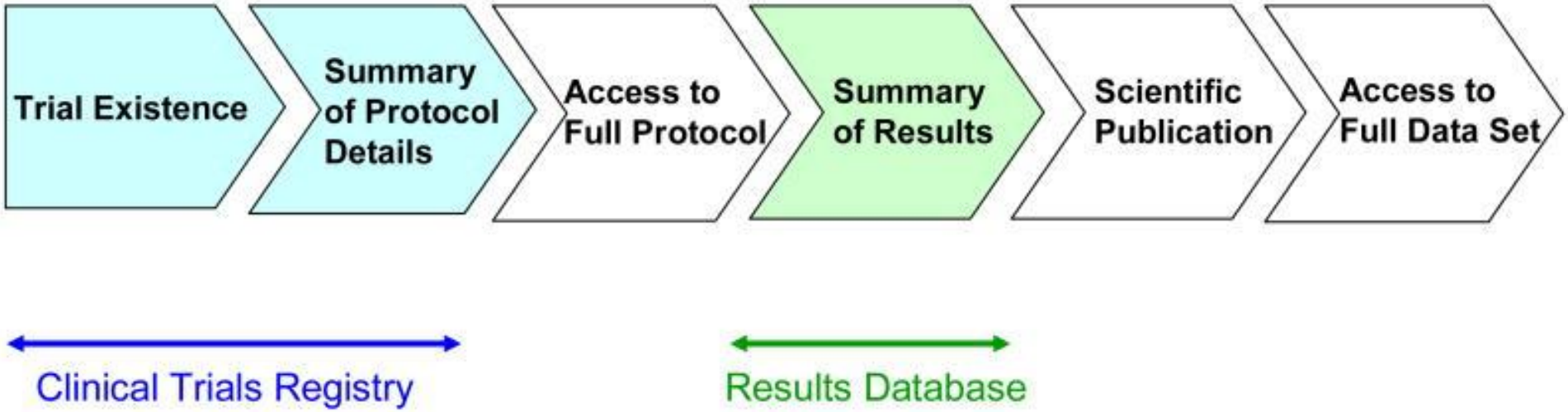
International Journal of Medical Students supports Declaration of transparency
30/01/2014

Sign-up to our newsletter
to keep up-to-date with with the latest developments by email.

http://www.espanol.equator-network.org/


عربي 中文 English Français Русский Español
World Health Organization
Media centre Publications Countries Programmes About WHO Search
International Clinical Trials Registry Platform (ICTRP)
Welcome to the WHO ICTRP
The mission of the WHO International Clinical Trials Registry Platform is to ensure that a complete view of research is accessible to all those involved in health care decision making.
WHO/P. Virot
ICTRP
Registry Network
Search for Trials
Subscribe
ANZCTR
Australian New Zealand Clinical Trials Registry
Home Login Contact us Feedback
Register Trial Trial Search Latest News FAQ About
Homepage
How to register a trial
How to update a trial
ANZCTR Statistics
Data Item Definitions
Links
Note that our website is currently experiencing compatibility issues with Windows 8 operating system and also with Internet Explorer 10. If you are using both or either of these, please click here for instructions on how to enable the compatibility view settings to overcome these issues. Alternatively, if available please use Internet Explorer 7, 8, or 9.
Welcome to the Australian New Zealand Clinical Trials Registry (ANZCTR)
The Australian New Zealand Clinical Trials Registry has been established at the NHMRC Clinical Trials Centre, University of Sydney, with funding from the Australian National Health and Medical Research Council (NHMRC) and New Zealand Health
ClinicalTrials.gov
A service of the U.S. National Institutes of Health
ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world. Learn more about clinical studies and about this site, including relevant history, policies, and laws.
Find Studies About Clinical Studies Submit Studies Resources About This Site
ClinicalTrials.gov currently lists 160,091 studies with locations in all 50 states and in 185 countries.
Text Size
Search for Studies
Example: "Heart attack" AND "Los Angeles"
Search
Advanced Search | See Studies by Topic
See Studies on a Map
Search Help
How to search
How to find results of studies
How to read a study record
Locations of Recruiting Studies
Non-U.S. Only (51%)
U.S. Only (43%)
Both U.S. & Non-U.S. (6%)
Total N = 32,112 studies
Data as of January 28, 2014
See more trends, charts, and maps
Learn More
ClinicalTrials.gov Online Training
Glossary of common site terms
For the Press
Using our RSS Feeds
For Patients & Families
How to find studies
See studies by topic
Learn about clinical studies
Learn more…
For Researchers
How to submit studies
Download content for analysis
About the results database
Learn more…
For Study Record Managers
Why register?
How to register study records
FDAAA 801 Requirements
Learn more…
HOME RSS FEEDS SITE MAP TERMS AND CONDITIONS DISCLAIMER CONTACT NLM HELP DESK
Copyright | Privacy | Accessibility | Viewers & Players | Freedom of Information Act | USA.gov
U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services
ISRCTN Search
ISRCTN Apply for ISRCTN
ISRCTN FAQs
The ISRCTN Register is owned by ISRCTN - a not-for-profit organisation. The scheme is administered on behalf of ISRCTN by Current Controlled Trials Ltd.
ISRCTN works with partners to improve the information publicly available about clinical trials.

Continuo de la Transparencia



Para que otros puedan ver quien le hizo que a quien y que paso (perjuicios y beneficios)

BMJ

Zarin DA, Tse T. Science 2008;319:1340-42

Declaración de Helsinki

35. Todo estudio de investigación con seres humanos debe **ser inscrito en una base de datos disponible al público antes** de aceptar a la primera persona.

Modificación del 2013

http://www.wma.net/es/30publications/10policies/b3/index.html

¿Porque Registrar los Estudios?

- Razones éticas
  - Responsabilidad hacia los participantes
  - Acceso a información sobre estudios completados o en proceso
  - Disponibilidad de información sin sesgo es un bien publico

¿Porque Registrar los Estudios?

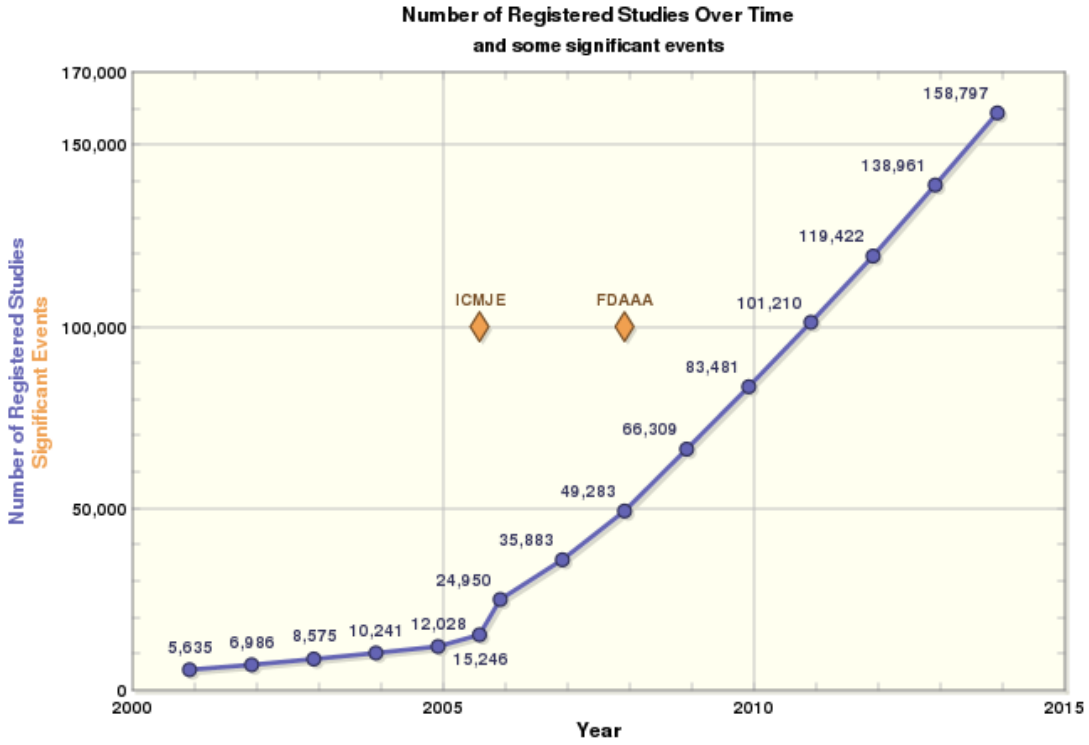
- Razones científicas
  - Minimizar exposición a riesgos identificados en estudios previos
  - Acelera el conocimiento
  - Identificar y desalentar la duplicación innecesaria de estudios y publicaciones
  - Evitar sesgos en la publicación
  - Proporcionar un medio para compara el protocolo original en el que se baso la aprobación ética
  - Promover la colaboración entre investigadores

Registro de Ensayos

Year	Policy	Impact
1997	FDA Modernization Act	Requiere registro
2000		Clinicaltrials.gov
2005	**ICMJE Policy**	**Registro prospectivo como condición para publicación**
2006	WHO ICTRP	Establece una red de registros y los datos mínimos
2007		ICTRP
2007	FDA Amendments Act	Expande los requisitos, establece base de datos de resultados
2008		Clinicaltrials.gov datos de resultados
2013	Helsinki Declaration	Párrafos 35 y 36
2013	EudraCT, EMA	Hará disponibles resultados de estudios

Registro de Ensayos

(Data as of January 28, 2014)



Clinicaltrials.gov

http://www.clinicaltrials.gov/ct2/resources/trends

Registros aceptables

- Disponibles al publico sin costo
- Abiertos a todos los interesados en registrarse
- Manejados por un grupo sin fin de lucro

ICMJE 2005, 2008, 2013

www.clinicaltrials.gov
www.anzctr.org.au
www.ISRCTN.org
www.umin.ac.jp/ctr/index/htm
www.trialregister.nl
https://eudract.ema.europa.eu/
(new registrations after 6/20/11)

Any of the **primary** registries that participate in the WHO ICTRP (starting 7/2007)

BMJ

Trial Registration: The BMJ

- In accordance with the… ICMJE Recommendations (2013), the *BMJ* will not consider reports of clinical trials unless they were registered prospectively before recruitment of any participants…

- The *BMJ*'s **criteria for a suitable public trial registry** are: free to access, searchable, and identifies trials with a unique number; registration is free or has minimal cost; registered information is validated; registered entry includes details to identify the trial and investigator and includes the status of the trial; and the research question, methodology, intervention, funding, and sponsorship must all be disclosed at registration.

- The *BMJ* **does not consider** posting of protocols and results in clinical trial registries to be **prior publication**.

Pero no Todos…

- Muestra aleatoria de 200 revistas
  - 71% no lo requieren
  - 28% lo requieren
  - 2% lo sugieren
- Causas
  - Miedo a perder
  - Pocos estudios
  - Estudios pequeños
  - Escepticismo sobre los beneficios

Wager E at al. BMJ 2013;347:f5248

Fallas resueltas por Registro Y Lineamientos

- No reportaje de estudios
- Reporte incompleto
  - Omisión de aspectos fundamentales (participantes, intervenciones, aleatorización)
  - Resultados parciales
  - Reporte incompleto de riesgos y daños
- Reportaje selectivo
  - Desenlace
  - Análisis

Fallas resueltas

- Informes engañosos
  - Mala interpretación de hallazgos, giro positivo
  - Incorrecta interpretación del diseño del estudio
  - Discrepancias no reconocidas entre distintas fuentes de información (protocolo, registro, manuscrito)

Revisión por Pares (Peer Review)

- “la evaluación de la originalidad y la interpretación de los hallazgos de investigación por expertos calificados”
    - Allchin D, 1993
- 1731 Medical Essays and Observations (RS of Edinburgh)
- 1893 BMJ
- Siglo XX- otras revistas

Declaración de Helsinki

36. Los investigadores, autores, auspiciadores, directores y editores todos tienen obligaciones éticas con respecto a la publicación y difusión de los resultados de su investigación. Los investigadores **tienen el deber de tener a la disposición del público los resultados de su investigación en seres humanos y son responsables de la integridad y exactitud de sus informes**… Los informes sobre investigaciones que no se ciñan a los principios descritos en esta Declaración no deben ser aceptados para su publicación.

http://www.wma.net/en/30publications/10policies/b3/index.html

Peer Review

- Lento
- Caro
- Derrochador del tiempo académico
- Altamente subjetivo
- Propenso al sesgo
- Abusado fácilmente
- Malo para detectar errores
- Casi inútil para detectar fraude

- Mas útil para mejorar lo que se publica que para separa al trigo de la paja

BMJ

Smith R. BMJ 1999;318:445:23-7

Peer Review

- Diferentes modelos
  - Doble Ciego
  - Abierto
  - Muy abierto
  - Después de la publicación

Peer Review

- Argumentos en pro del sistema abierto
  - Jueces secretos
  - Rendición de cuentas: enlace privilegio y deber
  - Crédito académico
  - Evita la dilación, el plagio

Peer Review

- Argumentos en contra
  - Menos critico
  - Efecto negativo en la relación entre colegas
  - Requiere mas tiempo

All unpublished manuscripts are confidential documents. If we invite you to review an article please do not discuss it even with a colleague: if you would like to pass it on to someone else to review please email papersadmin@bmj.com first.

Open peer review

We ask reviewers to sign their reports and declare any competing interests on any manuscripts we send them. Reviewers advise the editors, who make the final decision (aided by an editorial manuscript committee meeting for some articles, including original research).

For research papers, *The BMJ* has fully open peer review. This means that every accepted research paper submitted from September 2014 onwards will have its prepublication history posted alongside it on thebmj.com.

This prepublication history comprises all previous versions of the manuscript, the study protocol (submitting the protocol is mandatory for all clinical trials and encouraged for all other studies at *The BMJ*), the report from the manuscript committee meeting, the reviewers' signed comments, and the authors' responses to all the comments from reviewers and editors (read more in this editorial).

If you experience any adverse event arising from open peer review, or would like to tell us your views, please email papersadmin@bmj.com.

As a reviewer you will be advising the editors, who make the final decision (aided by an editorial committee for all research articles and most analysis articles). We will let you know our decision. Authors - and readers too, if the paper is accepted and published - will see your signed report, so please do not make any comments that you are not prepared to stand by publicly. Even if we do not accept an article we would like to pass on constructive comments that might help the author to improve it.

Autores

Autores: ICMJE 2013

- Substantial contributions to the conception or design of the work; or the **acquisition, analysis, or interpretation** of data for the work; AND
- **Drafting** the work or **revising** it critically for important intellectual content; AND
- Final **approval** of the version to be published; AND
- **Agreement to be accountable for all** aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

ICMJE Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals

Conflictos de Interés

- Existe un conflicto de intereses cuando el juicio profesional en relación con un interés primario (como el bienestar de los pacientes o la validez de la investigación) puede ser influenciado por un interés secundario (como el beneficio económico). Las percepciones de conflicto de intereses son tan importantes como los conflictos de intereses reales.
- Afectan a autores, revisores, editores

ICMJE Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals, 2013

Conflictos de Interés

- Relaciones financieras
  - Empleo
  - Consultoría
  - Posesión de acciones y opciones
  - Honorarios
  - Patentes
  - Testimonio experto pagado
- Personal
  - Relaciones y rivalidades
  - Competencia académica
  - Creencias intelectuales
- Acuerdos con los auspiciadores en cuanto al acceso a los datos

Declaration of Helsinki

36. … En la publicación se debe citar la fuente de financiamiento, afiliaciones institucionales y conflictos de intereses.

Modificada Oct 2013

http://www.wma.net/en/30publications/10policies/b3/index.html

Conflictos de Interés-The BMJ

"We believe that, to make the best decision on how to deal with an article, we should know about any competing interests that authors may have, and that if we publish the article readers should know about them too.

"We are not aiming to eradicate such interests; they are almost inevitable. We will not reject your article simply because you have a conflict of interest, but we want you to make a declaration on whether or not you have competing interests. (We also ask our staff and reviewers to declare any competing interests.)"

BMJ

http://www.bmj.com/about-bmj/resources-authors/forms-policies-and-checklists/declaration-competing-interests

About BMJ

- Editorial staff
- Advisory panels
- Publishing model
- Complaints procedure
- History of BMJ online
- Freelance contributors
- Poll archive
- Help for bmj.com visitors
- Evidence based publishing
- BMJ on the iPad
- Article clusters

Transparency policy

The mission of the *BMJ* is to lead the debate on health and to engage, inform, and stimulate all doctors and health care researchers in ways that enable them to make better decisions and improve outcomes for patients.

Underpinning these aims, the *BMJ* has a set of ethical editorial principles, an ethics advisory committee, and a commitment to transparency. We try to ensure that readers, authors, and editors know as much about the background to each other's work as possible. We do this through policies such as open peer review, declaring competing interests, and explaining the role of the bodies that fund research.

But there are many other policies and principles that help the *BMJ* to be an ethical publisher, and we have brought all of them together in this single transparency policy. You can reach the policies listed below simply by clicking on the links.

We will add to the *BMJ*'s transparency policy as often as we need to. Please contact us if you feel there is anything missing.

BMJ

BMJ 2013;347:f4796 doi: 10.1136/bmj.f4796 (Published 7 August 2013)

EDITORIALS

Declaration of transparency for each research article

OPEN ACCESS

An antidote to inadequate reporting of research

Douglas G Altman *director*[1], David Moher *senior scientist*[2]

[1]Centre for Statistics in Medicine, University of Oxford, Botnar Research Centre, Oxford, UK; [2]Clinical Epidemiology Program, Ottawa Hospital Research Institute, Ottawa Hospital - General Campus, Ottawa, ON K1H 8L6, Canada

Transparency declaration

The lead author* affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

*The manuscript's guarantor.

Altman DG & Moher D. BMJ 2013;347:f4796

Investigación Replicable

- Experimento replicable
  - Investigador independiente, data, métodos analíticos, instrumentos
- Investigación replicable
  - Investigadores independientes usan los mismos datos para análisis independientes

Epidemiologia→ Salud Publica→ Ensayos clínicos

- Verificar hallazgos publicados
- Hacer análisis independientes
- Eliminar criticas no validas
- Acelerar el intercambio de ideas

BMJ

Peng RD et al., Am J Epidemiol 2006

¿Porque Compartir Datos?

- Argumentos morales y éticos
  - Resultados de investigación como bien publico
    - Participantes se exponen a riesgos
    - La sociedad paga la investigación
- Argumentos prácticos y científicos
  - Maximizar el valor de los datos recabados
  - Verificar hallazgos
  - Aumentar la base de evidencia

NSF

Canadian Institutes of Health Research

FDA U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

NIH

DFG Deutsche Forschungsgemeinschaft

NHS Health Research Authority

wellcome trust

MRC Medical Research Council

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Australian Government
National Health and Medical Research Council

THE WILLIAM AND FLORA HEWLETT FOUNDATION

PhRMA
RESEARCH · PROGRESS · HOPE

efpia
European Federation of Pharmaceutical Industries and Associations

Principles for Responsible Clinical Trial Data Sharing
Our Commitment to Patients and Researchers

Biopharmaceutical companies are committed to enhancing public health through responsible sharing of clinical trial data in a manner that is consistent with the following Principles:

- Safeguarding the privacy of patients
- Respecting the integrity of national regulatory systems
- Maintaining incentives for investment in biomedical research

DORIS DUKE CHARITABLE FOUNDATION

BILL & MELINDA GATES *foundation*

La Responsabilidad de las Publicaciones

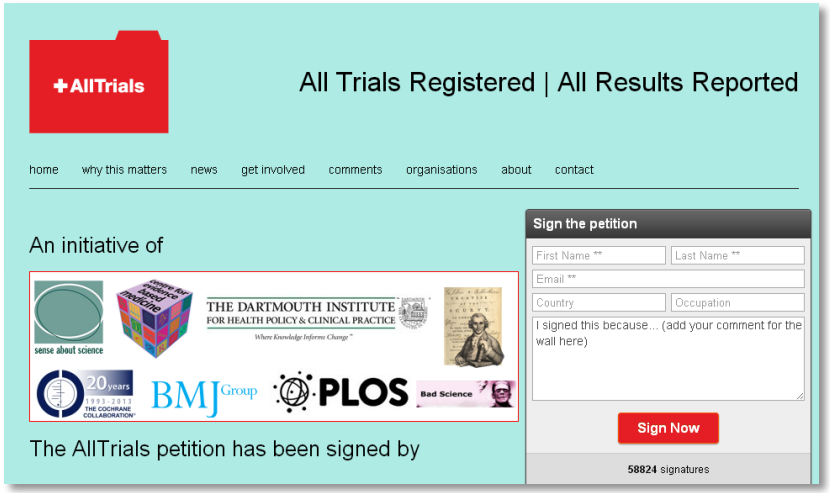
"Reproducibility should be the gold standard that all peer reviewers and editors aim for when assessing whether a manuscript has supplied sufficient information, about the underlying data and other materials, to allow others to repeat and build on the experiments."

www.parliament.uk

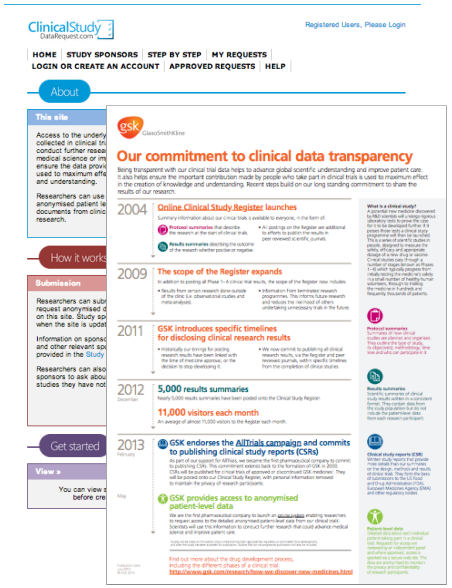
http://www.publications.parliament.uk/pa/cm201012/cmselect/cmsctech/856/85602.htm

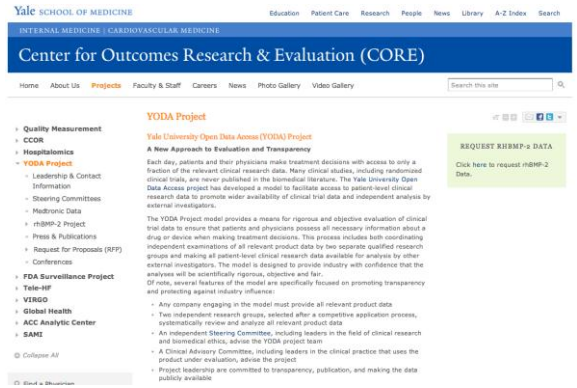
Open Trials

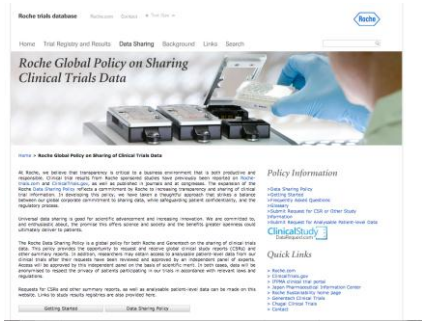
1. **Conocimiento que se hizo el estudio**
2. **Resumen de los hallazgos (revistas, documentos regulatorios)**
3. **Información mas detallada sobre métodos y resultados (CSR)**
4. IPD



Iniciativas







The BMJ and Open Data

2009	BMJ implements data sharing statements on all research papers
2011	BMJ Open launches and is first medical journal to integrate its submission process with the Dryad digital repository
2012	BMJ publishes special issue on hidden clinical trial data and some authors deposit data in Dryad
2013	BMJ Open data campaign launches
	The BMJ no longer publishes any trial of drugs or devices where the authors do not commit to making the relevant anoymised patient level data available

BMJ

BMJ

BMJ 2012;345:e7888 doi: 10.1136/bmj.e7888 (Published 20 November 2012) Page 1 of 2

EDITORIALS

The new *BMJ* policy on sharing data from drug and device trials

Is a necessary first step towards the full sharing of all anonymised trial data

Fiona Godlee *editor*, Trish Groves *deputy editor*

BMJ

Last month the *BMJ* announced a new policy on sharing data from clinical trials.[1] From January 2013, trials of drugs and medical devices will be considered for publication only if the authors commit to making the relevant anonymised patient level data available on reasonable request.[2] This new policy will apply to any paper that reports the main endpoints of a randomised controlled trial of one or more drugs or medical devices in current use, whether or not the trial was funded by industry (box).

Why the new policy? Because it is no longer possible to pretend that a report of a clinical trial in a medical journal is enough to allow full independent scrutiny of the results. Journals are, of course, not the only potential channel for such scrutiny, but as long as publication remains the main currency for academic recognition, journals have a responsibility to use what power they have to push for greater transparency. If research is to help doctors and patients make the best clinical decisions, it must be reliable and reproducible, but these are qualities that current peer review processes cannot assure.

Since announcing the new policy we have been asked why it applies only to trials of drugs and devices, what is meant by "relevant," and who will judge whether a request is "reasonable." We have started with drugs and devices as being the area of medicine where most evidence exists for incomplete and misleading trial publication, but we expect that the policy will extend to cover all clinical trials. "Relevant data" encompasses all anonymised data on individual patients on which the analysis, results, and conclusions reported in the paper are based. As for "reasonable request," the *BMJ* is not in a position to adjudicate, but we will expect requesters to submit a protocol for their re-analysis to the authors and to commit to making their results public. And we are at least able to make the transaction transparent. We will encourage those requesting data to send a rapid response to bmj.com describing what they are looking for. If the request is refused we will ask the authors of the paper to explain why.

Does the new policy represent a big change? The extensive media coverage would suggest so. But we see it as just one step up from our current policy: since 2009 we have encouraged authors to share their data on request and have required them to say whether they will or not. The results across the *BMJ* and *BMJ Open* have been promising: many of our authors now say that they will share their data on request, and one *BMJ* and 23 *BMJ Open* papers have datasets posted on Dryad, the digital repository with which we have partnered (http://datadryad.org). A survey of trialists published in the *BMJ* this week gives further cause for optimism. Joe Ross and colleagues emailed 683 corresponding authors of trials published in the six major general medical journals. About three quarters of the 317 who responded said that they thought data sharing through data repositories should be required, and a similar proportion said that data sharing should be required in response to individual requests.[3]

But the policy has clear limitations and is by no means the end of the story. The *BMJ* publishes relatively few trials of drugs and devices. Of the 226 research papers published so far this year, 31 were the main reports of randomised controlled trials, of which most were trials of health services. Six trials were of drugs, none were of devices, and only one of the drug trials was sponsored by industry.[4] The *BMJ*'s new policy is a signal, but it won't change things on its own. The *Annals of Internal Medicine* and *PLoS Medicine* both have policies on data sharing.[5,6] We hope that other journals will follow, and we look to the International Committee of Medical Journal Editors, of which the *BMJ* is a member, to take a decisive lead.

But because many trials never get published in journals at all,[7] real change will come only when the regulators raise their game. Here too there is scope for optimism. After pressure from the Nordic Cochrane Centre,[8] the European ombudsman ruled that the European Medicines Agency had been wrong to hold clinical trial data as commercial in confidence. The agency's new director general responded by announcing earlier this year that the agency would publish clinical trial data once a drug has been approved.[9] A workshop this week aims to hammer out the details.[10]

If patient anonymity is assured, the most efficient and effective option must be open deposition of patient level data with the underlying code and background documentation. However,

Correspondence to: T Groves tgroves@bmj.com

From January 2013, trials of drugs and medical devices will be considered for publication only if the authors commit to making the **relevant anonymized patient level data** available on **reasonable request**... This applies to any paper that reports the **main endpoints** of a RCT of one or more **drugs or medical devices** in current use, whether or not they are funded by industry.

BMJ

Godlee F, Groves T. *BMJ,* 2013

Journals

Annals of Internal Medicine

Established in 1927 by the American College of Physicians

To encourage transparency and reproducible research *Annals* will publish a **statement** with every original research article indicating the authors **willingness to share** the following items with the public: [Study protocol, statistical code, dataset.] Annals **does not require** the sharing of these items but we do require authors to state their willingness to share, and any conditions for sharing. (2007)

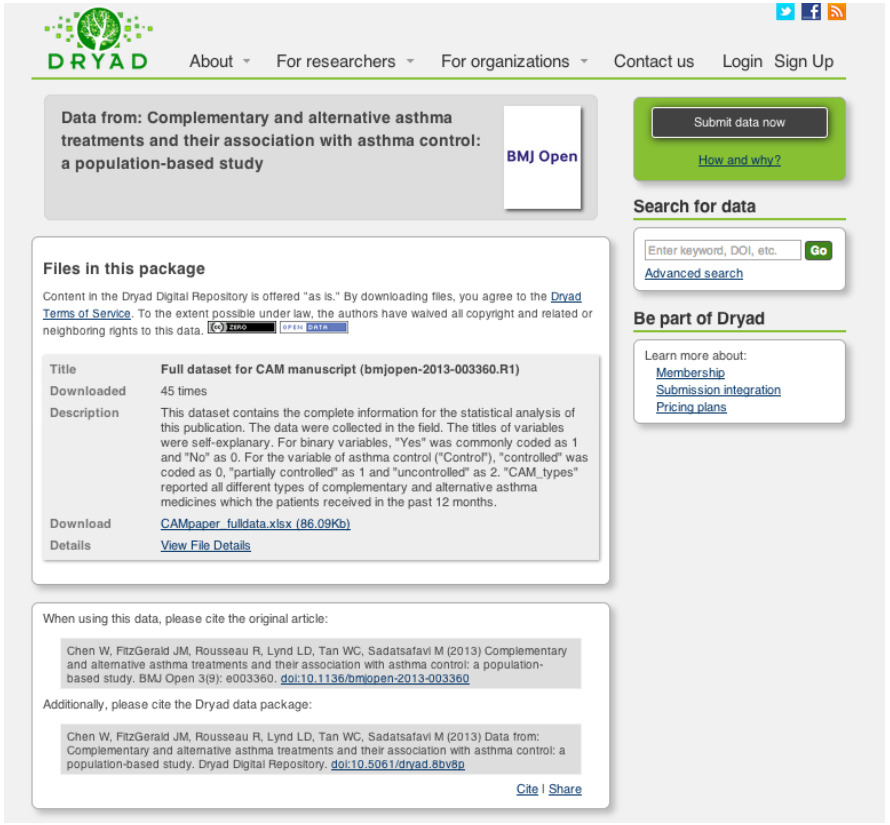
Journals

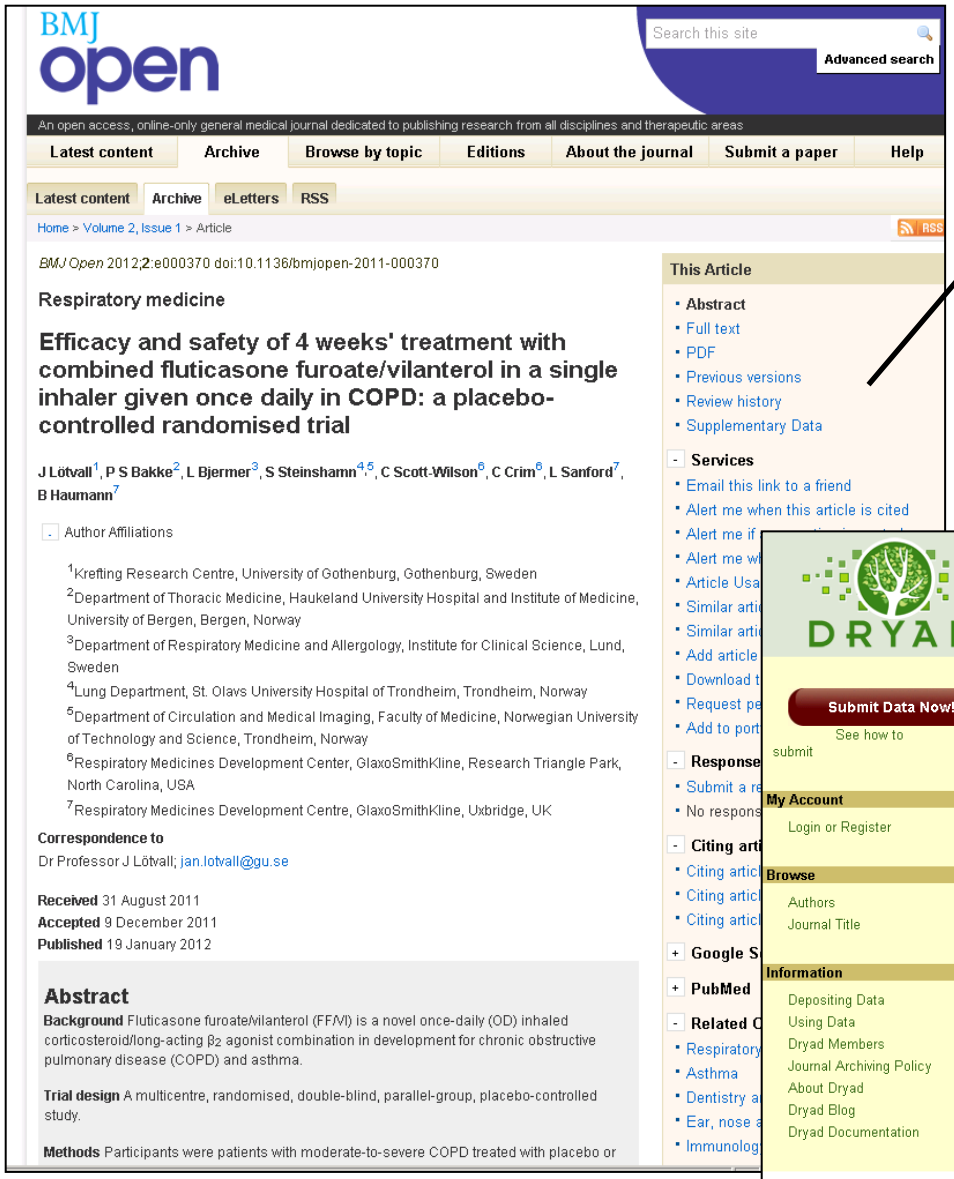
BMJ Open

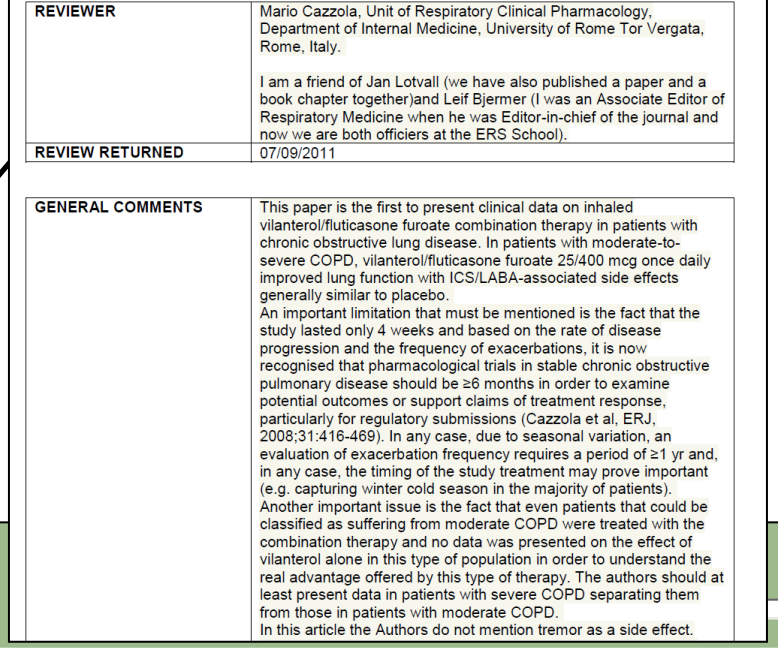
- All articles include a data sharing statement: "Technical appendix, statistical code, and underlying [or supplementary] dataset available [from the corresponding author or] at Dryad repository, who will provide a permanent, citable and open access home for the dataset”
- **Data deposition process is integrated with submission**
- Dryad digital repository http://datadryad.org/ provides a DOI to aid citation and provide a permanent link and uses CCO “No rights reserved” licence

Journals

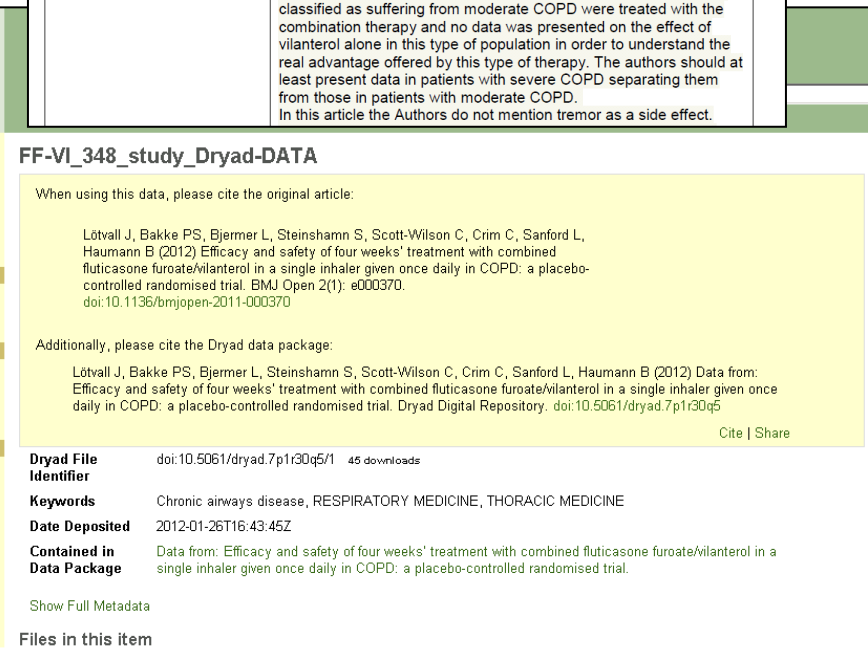

DRYAD
About
For researchers
For organizations
Contact us
Login
Sign Up
Search for data
Search terms
Enter keyword, author, title, DOI, etc. Example: herbivory
Go
Advanced Search
Refinements
Publication Name: BMJ Open
Results/page 10
Sort items by relevance
in order descending
Now showing items 1-10 of 56
1 2 3 4 . . . 6 Next Page >>
Dryad Data Packages (56)
KNB (0)
TreeBASE (0)
Chen W, FitzGerald JM, Rousseau R, Lynd LD, Tan WC, Sadatsafavi M (2013) Data from: Complementary and alternative asthma treatments and their association with asthma control: a population-based study. BMJ Open doi:10.5061/dryad.8bv8p
Joore IKCW, van Rooijen MS, Schim van der Loeff MF, de Neeling AJ, van Dam A, de Vries HJC (2013) Data from: Low prevalence of methicillin-resistant Staphylococcus aureus among men who have sex with men attending an STI clinic in Amsterdam, a cross-sectional study. BMJ Open doi:10.5061/dryad.569j0
Schroter S, Glasziou P, Heneghan C (2012) Data from: Quality of descriptions of treatments: a review of published randomised controlled trials. BMJ Open doi:10.5061/dryad.h85k0
Dmello D, Nayak RP, Matuschak GM (2011) Data from: Stratified assessment of the role of inhaled hypertonic saline in reducing cystic fibrosis pulmonary exacerbations: a retrospective analysis. BMJ Open doi:10.5061/dryad.491d1
Heneghan C, Thompson M, Billingsley M, Cohen D (2011) Data from: Medical-device recalls in the UK and the device-regulation process: retrospective review of safety notices and alerts. BMJ Open doi:10.5061/dryad.585t4
Ward DJ, Martino OI, Simpson S, Stevens AJ (2013) Data from: Decline in new drug launches: myth or reality? Retrospective observational study using 30 years of data from the UK. BMJ Open doi:10.5061/dryad.2263n
Wildt S, Krag A, Gluud L (2011) Data from: Characteristics of randomised trials on diseases in the digestive system registered in ClinicalTrials.gov - a retrospective analysis. BMJ Open doi:10.5061/dryad.s38s0g00
Refine Search
Author
Heneghan, Carl (2)
Taylor, Rod (2)
Aarø, Leif E. (1)
Aarø, Leif (1)
Abrams, Dominic (1)
Agnew, Rona (1)
Ahmed, Mehnaz Atiq (1)
Aitken, Debbie (1)
Alam, Muhmmad Matloob (1)
Almuzaini, Tariq (1)
... View More
Subject
Health policy (6)
PUBLIC HEALTH (6)
Quality in health care (6)
Epidemiology (4)
Public health (4)
EDUCATION & TRAINING (see Medical Education & Training) (3)
HEALTH ECONOMICS (3)
Health informatics (3)
Chronic airways disease (2)
Clinical governance (2)
... View More
Date Issued
2014 (3)
2013 (27)
2012 (17)
2011 (9)
Publication Name
BMJ Open (56)


DRYAD
About
For researchers
For organizations
Contact us
Login
Sign Up
Data from: Complementary and alternative asthma treatments and their association with asthma control: a population-based study
BMJ Open
Files in this package
Content in the Dryad Digital Repository is offered "as is." By downloading files, you agree to the Dryad Terms of Service. To the extent possible under law, the authors have waived all copyright and related or neighboring rights to this data.
Title
Full dataset for CAM manuscript (bmjopen-2013-003360.R1)
Downloaded
45 times
Description
This dataset contains the complete information for the statistical analysis of this publication. The data were collected in the field. The titles of variables were self-explanary. For binary variables, "Yes" was commonly coded as 1 and "No" as 0. For the variable of asthma control ("Control"), "controlled" was coded as 0, "partially controlled" as 1 and "uncontrolled" as 2. "CAM_types" reported all different types of complementary and alternative asthma medicines which the patients received in the past 12 months.
Download
CAMpaper_fulldata.xlsx (86.09Kb)
Details
View File Details
When using this data, please cite the original article:
Chen W, FitzGerald JM, Rousseau R, Lynd LD, Tan WC, Sadatsafavi M (2013) Complementary and alternative asthma treatments and their association with asthma control: a population-based study. BMJ Open 3(9): e003360. doi:10.1136/bmjopen-2013-003360
Additionally, please cite the Dryad data package:
Chen W, FitzGerald JM, Rousseau R, Lynd LD, Tan WC, Sadatsafavi M (2013) Data from: Complementary and alternative asthma treatments and their association with asthma control: a population-based study. Dryad Digital Repository. doi:10.5061/dryad.8bv8p
Cite | Share
Submit data now
How and why?
Search for data
Enter keyword, DOI, etc.
Go
Advanced search
Be part of Dryad
Learn more about:
Membership
Submission integration
Pricing plans


BMJ open
Search this site
Advanced search
An open access, online-only general medical journal dedicated to publishing research from all disciplines and therapeutic areas
Latest content
Archive
Browse by topic
Editions
About the journal
Submit a paper
Help
Latest content
Archive
eLetters
RSS
Home > Volume 2, Issue 1 > Article
BMJ Open 2012;2:e000370 doi:10.1136/bmjopen-2011-000370
Respiratory medicine
Efficacy and safety of 4 weeks' treatment with combined fluticasone furoate/vilanterol in a single inhaler given once daily in COPD: a placebo-controlled randomised trial
J Lötvall[1], P S Bakke[2], L Bjermer[3], S Steinshamn[4,5], C Scott-Wilson[6], C Crim[6], L Sanford[7], B Haumann[7]
Author Affiliations
[1]Krefting Research Centre, University of Gothenburg, Gothenburg, Sweden
[2]Department of Thoracic Medicine, Haukeland University Hospital and Institute of Medicine, University of Bergen, Bergen, Norway
[3]Department of Respiratory Medicine and Allergology, Institute for Clinical Science, Lund, Sweden
[4]Lung Department, St. Olavs University Hospital of Trondheim, Trondheim, Norway
[5]Department of Circulation and Medical Imaging, Faculty of Medicine, Norwegian University of Technology and Science, Trondheim, Norway
[6]Respiratory Medicines Development Center, GlaxoSmithKline, Research Triangle Park, North Carolina, USA
[7]Respiratory Medicines Development Centre, GlaxoSmithKline, Uxbridge, UK
Correspondence to
Dr Professor J Lötvall; jan.lotvall@gu.se
Received 31 August 2011
Accepted 9 December 2011
Published 19 January 2012
Abstract
Background Fluticasone furoate/vilanterol (FF/VI) is a novel once-daily (OD) inhaled corticosteroid/long-acting β2 agonist combination in development for chronic obstructive pulmonary disease (COPD) and asthma.
Trial design A multicentre, randomised, double-blind, parallel-group, placebo-controlled study.
Methods Participants were patients with moderate-to-severe COPD treated with placebo or
This Article
Abstract
Full text
PDF
Previous versions
Review history
Supplementary Data
Services
Email this link to a friend
Alert me when this article is cited
Alert me if
Alert me wh
Article Usa
Similar artic
Similar artic
Add article
Download t
Request pe
Add to port
Response
Submit a re
No respons
Citing arti
Citing articl
Citing articl
Citing articl
Google S
PubMed
Related C
Respiratory
Asthma
Dentistry a
Ear, nose a
Immunolog


VERSION 1 - REVIEW
REVIEWER
Mario Cazzola, Unit of Respiratory Clinical Pharmacology, Department of Internal Medicine, University of Rome Tor Vergata, Rome, Italy.
I am a friend of Jan Lotvall (we have also published a paper and a book chapter together)and Leif Bjermer (I was an Associate Editor of Respiratory Medicine when he was Editor-in-chief of the journal and now we are both officiers at the ERS School).
REVIEW RETURNED
07/09/2011
GENERAL COMMENTS
This paper is the first to present clinical data on inhaled vilanterol/fluticasone furoate combination therapy in patients with chronic obstructive lung disease. In patients with moderate-to-severe COPD, vilanterol/fluticasone furoate 25/400 mcg once daily improved lung function with ICS/LABA-associated side effects generally similar to placebo.
An important limitation that must be mentioned is the fact that the study lasted only 4 weeks and based on the rate of disease progression and the frequency of exacerbations, it is now recognised that pharmacological trials in stable chronic obstructive pulmonary disease should be ≥6 months in order to examine potential outcomes or support claims of treatment response, particularly for regulatory submissions (Cazzola et al, ERJ, 2008;31:416-469). In any case, due to seasonal variation, an evaluation of exacerbation frequency requires a period of ≥1 yr and, in any case, the timing of the study treatment may prove important (e.g. capturing winter cold season in the majority of patients).
Another important issue is the fact that even patients that could be classified as suffering from moderate COPD were treated with the combination therapy and no data was presented on the effect of vilanterol alone in this type of population in order to understand the real advantage offered by this type of therapy. The authors should at least present data in patients with severe COPD separating them from those in patients with moderate COPD.
In this article the Authors do not mention tremor as a side effect.

DRYAD
Submit Data Now!
See how to submit
My Account
Login or Register
Browse
Authors
Journal Title
Information
Depositing Data
Using Data
Dryad Members
Journal Archiving Policy
About Dryad
Dryad Blog
Dryad Documentation


FF-VI_348_study_Dryad-DATA
When using this data, please cite the original article:
Lötvall J, Bakke PS, Bjermer L, Steinshamn S, Scott-Wilson C, Crim C, Sanford L, Haumann B (2012) Efficacy and safety of four weeks' treatment with combined fluticasone furoate/vilanterol in a single inhaler given once daily in COPD: a placebo-controlled randomised trial. BMJ Open 2(1): e000370. doi:10.1136/bmjopen-2011-000370
Additionally, please cite the Dryad data package:
Lötvall J, Bakke PS, Bjermer L, Steinshamn S, Scott-Wilson C, Crim C, Sanford L, Haumann B (2012) Data from: Efficacy and safety of four weeks' treatment with combined fluticasone furoate/vilanterol in a single inhaler given once daily in COPD: a placebo-controlled randomised trial. Dryad Digital Repository. doi:10.5061/dryad.7p1r30q5
Cite | Share
Dryad File Identifier
doi:10.5061/dryad.7p1r30q5/1 45 downloads
Keywords
Chronic airways disease, RESPIRATORY MEDICINE, THORACIC MEDICINE
Date Deposited
2012-01-26T16:43:45Z
Contained in Data Package
Data from: Efficacy and safety of four weeks' treatment with combined fluticasone furoate/vilanterol in a single inhaler given once daily in COPD: a placebo-controlled randomised trial.
Show Full Metadata
Files in this item
Files
Size
Format
View
Description
FF-VI_348_study_Dryad-DATA.pdf
153.0Kb
PDF
View/Open
dataset-file
To the extent possible under law, the authors have waived all copyright and related or neighboring rights to this data.

Journals

PLOS | MEDICINE

"Publication is conditional upon the agreement of the authors to **make freely available** any materials and information described in their publication that may be reasonably requested by others for the purpose of academic, non-commercial research… authors must comply with current best practice in their discipline for the **sharing of data** through databases: for example, deposition of microarray data in ArrayExpress or GEO; deposition of gene sequences in GenBank, EMBL or DDBJ; and deposition of ecological data in Dryad…"

http://www.plosmedicine.org/static/policies#sharing

Journals

- **All data** necessary to understand, assess, and extend the conclusions of the manuscript must be **available** to any reader of *Science*. All **computer codes** involved in the creation or analysis of data must also be available to any reader of *Science*. After publication, all reasonable requests for data and materials must be fulfilled. Any restrictions on the availability of data, codes, or materials, including fees and original data obtained from other sources (Materials Transfer Agreements), must be disclosed to the editors upon submission.

Journals

nature.com

- An inherent principle of publication is that others should be able to replicate and build upon the authors' published claims. Therefore, a condition of publication in a Nature journal is that **authors are required to make materials, data and associated protocols promptly available to readers without undue qualifications**. Any restrictions on the availability of materials or information must be disclosed to the editors at the time of submission. Any restrictions must **also** be disclosed in the submitted manuscript, including details of how readers can obtain materials and information. If materials are to be distributed by a for-profit company, this must be stated in the paper.

http://www.nature.com/authors/policies/availability.html

www.nature.com/scientificdata/about/

Apps | ScholarOne | pubmed | Welch | Blogs | Mail | BMJ | Exercise | Journals | Mail & VPN | News | Research stuff | Otros | Other

SCIENTIFIC DATA

Search Go

Home | About | For Authors | For Referees | Advisory and Editorial Board | Open Access | FAQ

About

▼Aims and Scope ▼Contacts ▼Advisory and Editorial Board ▼Supported by ▼FAQ

Launching in May 2014 and open now for submissions, *Scientific Data* is a new open-access, online-only publication for descriptions of scientifically valuable datasets, initially focusing on the life, biomedical and environmental science communities.

Scientific Data exists to help you publish, discover and reuse research data and is built around six key principles:

- Credit: Credit, through a citable publication, for depositing and sharing your data
- Reuse: Complete, curated and standardized descriptions enable the reuse of your data
- Quality: Rigorous community-based peer review
- Discovery: Find datasets relevant to your research
- Open: Promotes and endorses open science principles for the use, reuse and distribution of your data, and is available to all through a Creative Commons license
- Service: In-house curation, rapid peer-review and publication of your data descriptions

Scientific Data is accepting submissions

Submit manuscript ▶

Sign up for Scientific Data e-alert ▶

Scientific Data Updates

Scientific Data calls for submissions
October 8, 2013

Can you help us with our publication layout?
October 4, 2013

The Data Descriptor – making your data reusable
September 19, 2013

Scientific Data releases two sample Data Descriptors
September 11, 2013

Environmental, geoscience, & ecology scientists join Scientific Data's Editorial Board

Code of Conduct
Flowcharts
Guidelines
International standards for editors and authors
eLearning
Discussion Documents
COPE Digest
Seminars
COPE Research Grant
Resources and Further Reading

Resources

From our Code of Conduct and our Guidelines to useful sample letters and flowcharts, COPE offers a range of useful tools for journal editors and writers.

1,2,3,4,5

Guidelines

Access COPE's official guidance, including the Retraction Guidelines.

Flowcharts

Our flowcharts are designed to help editors follow COPE's Code of Conduct and implement its advice when faced with cases of suspected misconduct.

eLearning

COPE's eLearning course is now live. Designed to give editors a deeper understanding about publication ethics and practical guidance about how to detect, prevent and handle misconduct.

Code of Conduct

Ethical Editing Newsletters

COPE is committed to improving communication with its members about its activities and encouraging

Seminars

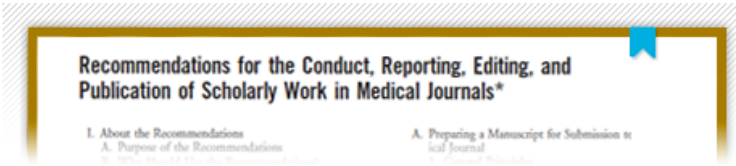
Details of COPE seminars and presentations from the past few years

ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

Enter search terms SEARCH

Recommendations | Conflicts of Interest | Journals Following the ICMJE Recommendations | About ICMJE | News & Editorials

Recommendations



Read the Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly work in Medical Journals.

BROWSE DOWNLOAD

Conflicts of Interest

Use the ICMJE Form for Disclosure of Potential Conflicts of Interest to generate a disclosure statement for your manuscript.

USING THE FORM DOWNLOAD

News & Editorials

ANNOUNCEMENT

Guiding Principles for the Development of Policies on Sharing Clinical Trials Data - *January, 2014*

Member Publications & Organizations

http://www.icmje.org/

Events
Becoming a Member
Announcements
WAME Listserve
Policies and Resources

WAME
world association of medical editors

A global association of editors of peer-reviewed medical journals who seek to foster cooperation and communication among editors, improve editorial standards, promote professionalism in medical editing through education, self-criticism, and self-regulation, and encourage research on the principles and practice of medical editing.

News »

New Board Members
New WAME Board Members for 2014-2015 were announced.
Details

The Principles of Transparency and Best Practice in Scholarly Publishing
A statement drafted by WAME, COPE, DOAJ, and OASPA
Details

WAME Strategic Planning Meeting
The WAME Board and team members met for a Strategic Planning Meeting on 6-7 September 2013 in Dallas, Texas, USA.
Details

Thank you

jmerino@bmj.com

@JG_Merino

BMJ