XIII Jornadas APDIS

Bibliotecas da Saúde
Da Ciência Aberta à Investigação
e Prática Clínica

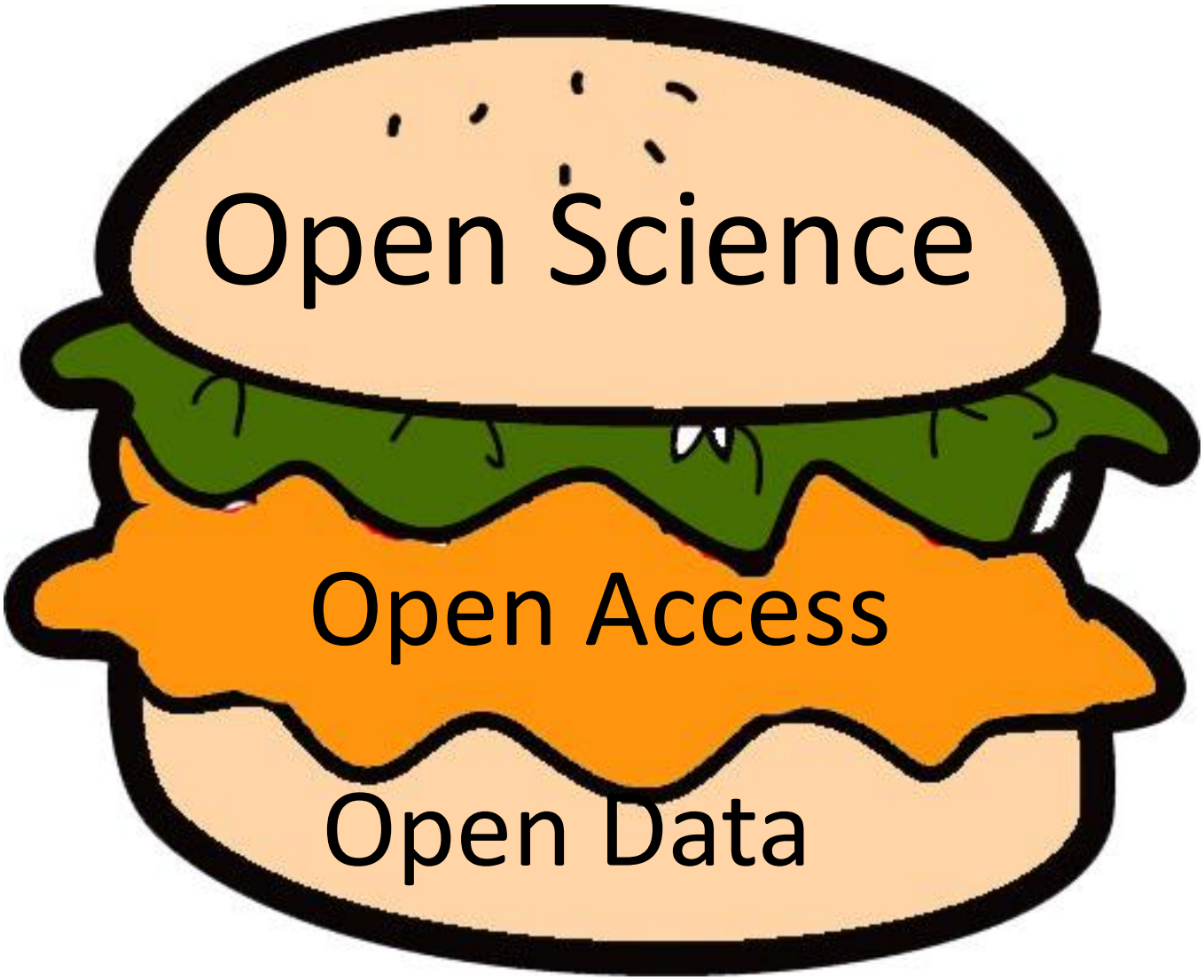
14 - 16 MARÇO 2018

ESTeSL - Lisboa

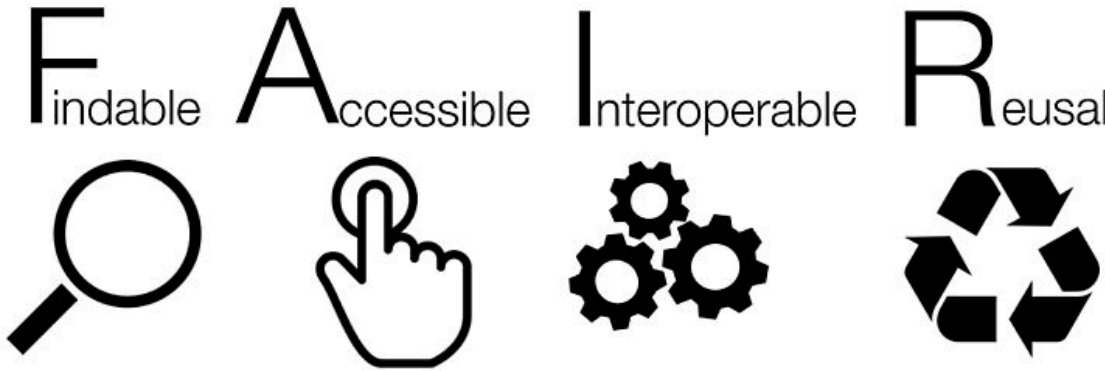
O acesso aberto é bom para a saúde
El acceso abierto es bueno para la salud

CSIC Remedios Melero

FOSTER


Open Science
Open Access
Open Data

"Open-access (OA) literature is digital, online, free of charge, and free of most copyright and licensing restrictions"



Principios FAIR

https://www.force11.org/group/fairgroup/fairprinciples

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UNDERSTAND ›

EDUCATE ›

Methodology

Video Gallery

FAQs

About / Contact

http://www.copyrightuser.org/video-gallery/

Rutas open access

- Declaración de Budapest
- Declaración de Berlín
- Declaración de Bethesda
- Declaración de Granada…
- …….
- Declación de Sant Joan….

open access

Pago por publicar (APCs)

Researcher decides where to publish

Check SHERPA RoMEO to see what OA and self-archiving options are available
www.sherpa.ac.uk/romeo

Publish in an open access journal

Pay Article Processing Charge (APC) - *if required*

Immediate open access (via publisher)

GOLD OA ROUTE

GREEN OA ROUTE

Publish in a subscription-based journal

Search for a repository
http://service.re3data.org/search
and http://www.opendoar.org

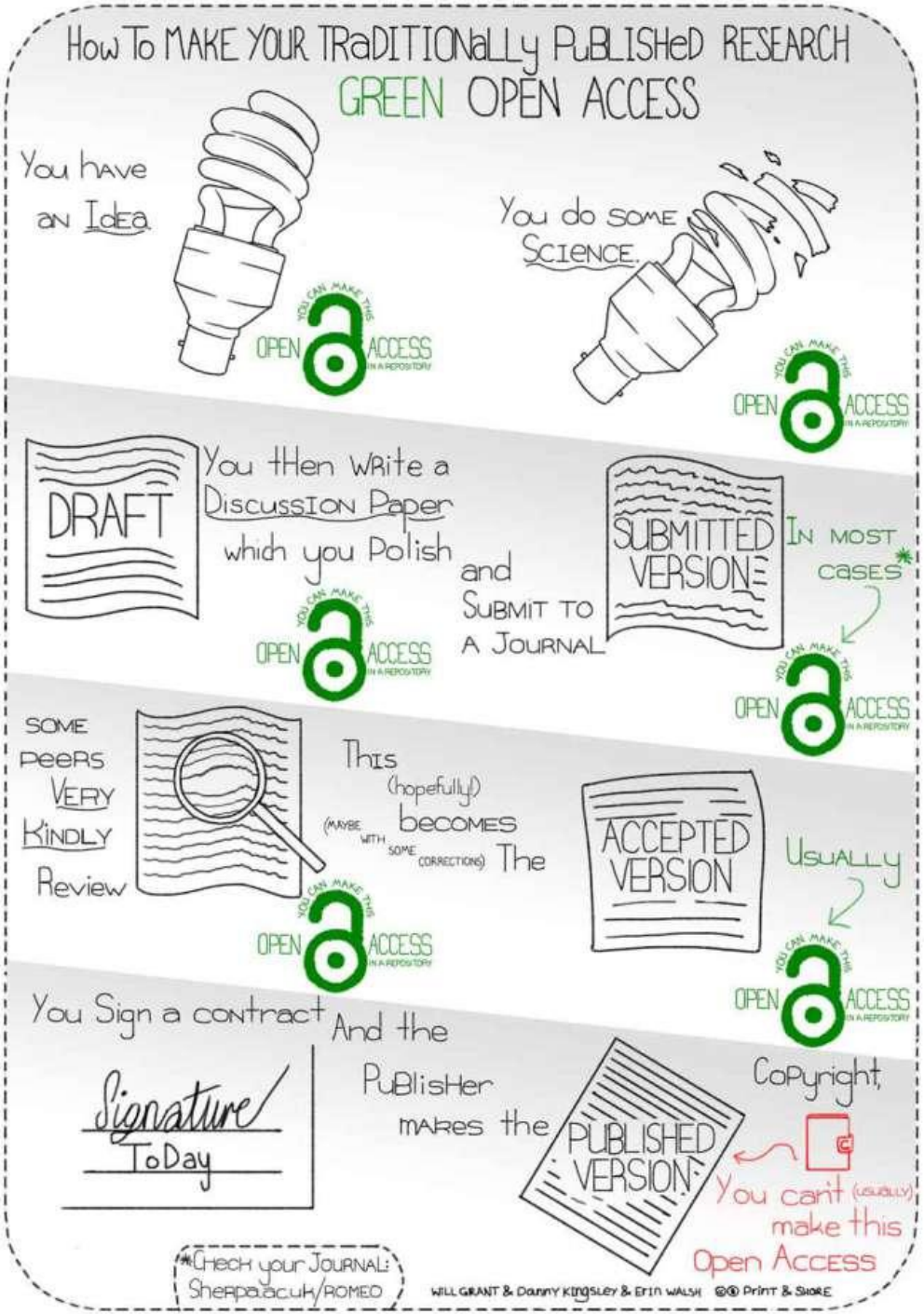
Self-archive in a repository, based on publisher policy.

Immediate or delayed open access, based on publisher's policy and any embargo period imposed

IF OPTION EXISTS
e.g. a 'hybrid' journal
(*a subscription-based journal that has a paid open access option*)

Pay Article Processing Charge (APC)

Immediate open access (via publisher)


How To MAKE YOUR TRaDITIONaLLy PuBLISHeD RESEARCH
GREEN OPEN ACCESS
You have an Idea
You do some Science.
OPEN ACCESS
DRAFT
You tHen wRite a Discussion Paper which you Polish
and Submit to a Journal
SUBMITTED VERSION
In most cases*
SOME peeRS VERY KINDLY Review
This (hopefully) becomes (MAYBE WITH SOME CORRECTIONS) The
ACCEPTED VERSION
Usually
You Sign a contract
Signature ToDay
And the Publisher makes the
PUBLISHED VERSION
Copyright
You can't (usually) make this Open Access
*Check your Journal: Sherpa.ac.uk/ROMEO
WILL GRANT & Danny Kingsley & Erin Walsh Print & Share

Journal Selector

Use the options below to find journals that match your requirements. The journals included in the tool are listed at the bottom of the page. Change the options for any of the questions and click Search. The journals list will update to give only the journals that fit your criteria. Click on a journal name for more information about it.

An explanation of the various options and abbreviations is here, or click on the question marks on the right.

+ Subject ?

+ Peer review ?

— Open access ?

Would you like the option for your paper to be free to read?
- (•) Yes
- ( ) No
- ( ) Don't mind

Would you like a journal that allows archiving of the peer reviewed author manuscript in a repository?
- (•) Don't mind

Is it important to you that the APC can be waived if the author can prove an inability to pay?

Is it important to you that the journal has a membership system for payment of APCs?
- (•) Yes
- ( ) No

Do you want a fully gold open access journal or a hybrid journal?
- (•) Fully open access
- ( ) Hybrid
- ( ) Subscription only
- ( ) Don't mind

Which licence would you like to be available to you for your paper?
- (•) CC BY
- ( ) CC BY-NC
- ( ) CC BY-NC-ND
- ( ) Copyright journal
- ( ) Another licence
- ( ) Don't mind

http://cofactorscience.com/journal-selector

THINK CHECK SUBMIT

Choose the right journal for your research

Home | Think | Check | Submit | About | Languages

Sharing research results with the world is key to the progress of your discipline and career. But with so many publications, how can you be sure you can trust a particular journal? Follow this check list to make sure you choose trusted journals for your research.

THINK

Are you submitting your research to a trusted journal?
Is it the right journal for your work?

CHECK

Use our check list to assess the journal

SUBMIT

http://thinkchecksubmit.org/

How open is a journal based on its 'OA spectrum'……..

HowOpenIsIt? Open Access Spectrum Tool

Access	Reader Rights	Reuse Rights	Copyrights	Author Posting Rights	Automatic Posting	Machine Readability	Access
OPEN ACCESS	Free readership rights to all articles immediately upon publication	Generous reuse & remixing rights (e.g., CC BY license)	Author holds copyright with no restrictions	Author may post any version to any repository or website	Journals make copies of articles automatically available in trusted third-party repositories (e.g., PubMed Central) immediately upon publication	Article full text, metadata, citations, & data, including supplementary data, provided in community machine-readable standard formats through a community standard API or protocol	OPEN ACCESS
	Free readership rights to all articles after an embargo of no more than 6 months	Reuse, remixing, & further building upon the work subject to certain restrictions & conditions (e.g., CC BY-NC & CC BY-SA licenses)	Author holds copyright, with some restrictions on author reuse of published version	Author may post final version of the peer-reviewed manuscript ("postprint") to any repository or website	Journals make copies of articles automatically available in trusted third-party repositories (e.g., PubMed Central) within 6 months	Article full text, metadata, citations, & data, including supplementary data, may be crawled or accessed through a community standard API or protocol	
	Free readership rights to all articles after an embargo greater than 6 months	Reuse (no remixing or further building upon the work) subject to certain restrictions and conditions (e.g., CC BY-ND license)	Publisher holds copyright, with some allowances for author and reader reuse of published version	Author may post final version of the peer-reviewed manuscript ("postprint") to certain repositories or websites	Journals make copies of articles automatically available in trusted third-party repositories (e.g., PubMed Central) within 12 months	Article full text, metadata, & citations may be crawled or accessed without special permission or registration	
	Free and immediate readership rights to some, but not all, articles (including "hybrid" models)	———	Publisher holds copyright, with some allowances for author reuse of published version	Author may post submitted version/draft of final work ("preprint") to certain repositories or websites	———	Article full text, metadata, & citations may be crawled or accessed with permission	
CLOSED ACCESS	Subscription, membership, pay-per-view, or other fees required to read all articles	No reuse rights beyond fair use/ limitations & exceptions to copyright (all rights reserved copyright) to read	Publisher holds copyright, with no author reuse of published version beyond fair use	Author may not deposit any versions to repositories or websites	No automatic posting in third-party repositories	Article full text & metadata not available in machine-readable format	CLOSED ACCESS

https://www.plos.org/how-open-is-it

https://oa2020.org/

VISION

OA2020 is a global alliance committed to **accelerating the transition to open access**.

FOAA
Fair Open Access Alliance

Fair Open Access

https://fairoa.org/

The Fair Open Access Principles

- Transparencia respecto a quien pertenece la revista
- Los autores de los artículos de la revista conservan los derechos de autor.
- Todos los artículos se publican de acceso abierto y se utiliza una licencia explícita de acceso abierto.
- El envío de originales y su publicación no está condicionada al pago de una tasa por el autor o por la institución a la que pertenece, o por la pertenencia a una institución o sociedad.
- Las tasas por publicar (APCs) deben ser bajas, transparentes y en proporción al trabajo realizado.

https://cos.io/our-services/top-guidelines/

TOC guidelines

Transparency, open sharing, and reproducibility are core values of science, but not always part of daily practice. Journals, funders, and scholarly societies can increase reproducibility of research by adopting the Transparency and Openness Promotion (TOP) Guidelines and helping them evolve to meet the needs of researchers and publishers while pursuing the most transparent practices.

Transparency and openness promotion guidelines

http://science.sciencemag.org/content/348/6242/1422.full

Summary of the eight standards and three levels of the TOP guidelines

Levels 1 to 3 are increasingly stringent for each standard. Level 0 offers a comparison that does not meet the standard.

	LEVEL 0	LEVEL 1	LEVEL 2	LEVEL 3
Citation standards	Journal encourages citation of data, code, and materials—or says nothing.	Journal describes citation of data in guidelines to authors with clear rules and examples.	Article provides appropriate citation for data and materials used, consistent with journal's author guidelines.	Article is not published until appropriate citation for data and materials is provided that follows journal's author guidelines.
Data transparency	Journal encourages data sharing—or says nothing.	Article states whether data are available and, if so, where to access them.	Data must be posted to a trusted repository. Exceptions must be identified at article submission.	Data must be posted to a trusted repository, and reported analyses will be reproduced independently before publication.
Analytic methods (code) transparency	Journal encourages code sharing—or says nothing.	Article states whether code is available and, if so, where to access them.	Code must be posted to a trusted repository. Exceptions must be identified at article submission.	Code must be posted to a trusted repository, and reported analyses will be reproduced independently before publication.
Research materials transparency	Journal encourages materials sharing—or says nothing	Article states whether materials are available and, if so, where to access them.	Materials must be posted to a trusted repository. Exceptions must be identified at article submission.	Materials must be posted to a trusted repository, and reported analyses will be reproduced independently before publication.
Design and analysis transparency	Journal encourages design and analysis transparency or says nothing.	Journal articulates design transparency standards.	Journal requires adherence to design transparency standards for review and publication.	Journal requires and enforces adherence to design transparency standards for review and publication.
Preregistration of studies	Journal says nothing.	Journal encourages preregistration of studies and provides link in article to preregistration if it exists.	Journal encourages preregistration of studies and provides link in article and certification of meeting preregistration badge requirements.	Journal requires preregistration of studies and provides link and badge in article to meeting requirements.
Preregistration of analysis plans	Journal says nothing.	Journal encourages preanalysis plans and provides link in article to registered analysis plan if it exists.	Journal encourages preanalysis plans and provides link in article and certification of meeting registered analysis plan badge requirements.	Journal requires preregistration of studies with analysis plans and provides link and badge in article to meeting requirements.
Replication	Journal discourages submission of replication studies—or says nothing.	Journal encourages submission of replication studies.	Journal encourages submission of replication studies and conducts blind review of results.	Journal uses Registered Reports as a submission option for replication studies with peer review before observing the study outcomes.

Increase effort , transparency and quality

PRINCIPLES OF TRANSPARENCY
& Best Practice in Scholarly Publishing

COPE

Committee on Publication Ethics (COPE), the Directory of Open Access Journals (DOAJ), the Open Access Scholarly Publishers Association (OASPA), and the World Association of Medical Editors (WAME) are scholarly organizations. All have seen increases in the number, and range in quality, of membership applications. Our organizations have collaborated to identify Principles of Transparency & Best Practice for Scholarly Publications. These principles form the basis of the criteria by which suitability for membership is assessed by COPE, DOAJ and OASPA, and part of the criteria on which membership applications are evaluated by WAME.

WEBSITE

A Journal's website, including the text that it contains, shall demonstrate that care has been taken to ensure high ethical and professional standards.

It should:
- contain an 'Aims & Scope' statement and the readership clearly defined.
- include a statement on what a journal will consider for publication including authorship criteria e.g. not multiple submissions, redundant publications)
- ISSNs displayed clearly (separate for print and electronic).

It must not:
- contain information that might mislead readers or authors.
- attempt to mimic another journal/ publisher's site.

NAME OF JOURNAL

The Journal name shall be unique.

It must not:
- be one that is easily confused with another journal.
- mislead potential authors and readers about the Journal's origin or association with other journals.

PEER REVIEW PROCESS

Journal content must be clearly marked as whether peer reviewed or not. Peer review is defined as obtaining advice on individual manuscripts from reviewers expert in the field who are not part of the journal's editorial staff.

The journal's website should:
- clearly describe this process, as well as any policies related to the journal's peer review procedures including the method of peer review used.

The journal's website should not:
- guarantee manuscript acceptance or very short peer review times.

OWNERSHIP AND MANAGEMENT

Information about the ownership and/or management of a journal shall be clearly indicated on the journal's website.

Publishers should not:
- use organizational or journal names that would mislead potential authors and editors about the nature of the journal's owner.

GOVERNING BODY

Journals shall have editorial boards or other governing bodies whose members are recognized experts in the subject areas included within the journal's scope.

The journal's website should:
- show full names and affiliations of the journal's editorial board or other governing body.

EDITORIAL TEAM/CONTACT INFORMATION

Journals shall provide the full names and affiliations of the journal's editors on the journal website as well as contact information for the editorial office, including a full address.

COPYRIGHT AND LICENSING

The policy for copyright shall be clearly stated in the author guidelines and the copyright holder named on all published articles.

The journal's website should:
- show licensing information clearly described in guidelines.

Licensing terms shall be indicated on all published articles, both HTML and PDFs.

If authors are allowed to publish under a Creative Commons license then any specific license requirements shall be noted. Any policies on posting of final accepted versions or published articles on third party repositories shall be clearly stated.

AUTHOR FEES

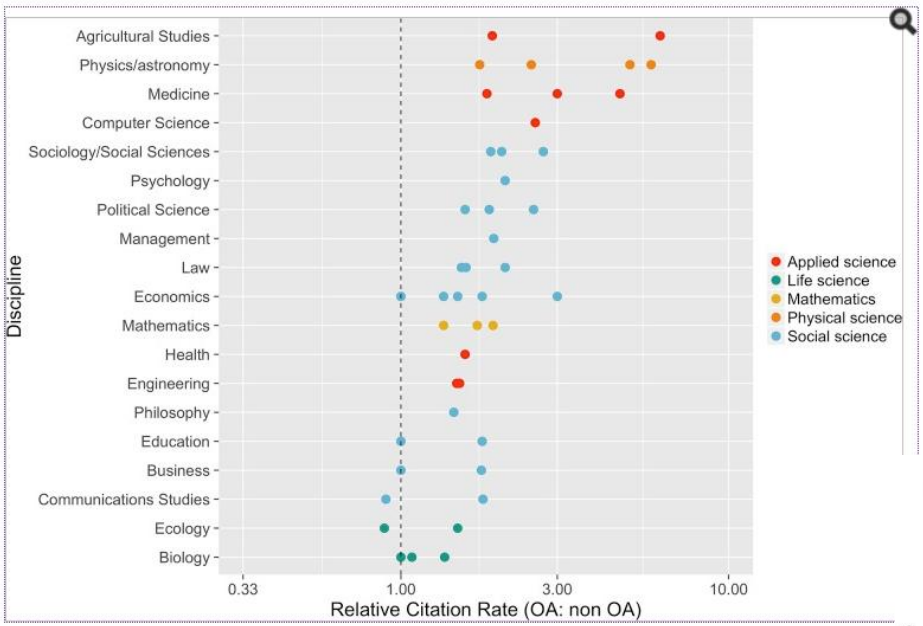
Any fees or charges that are required for manuscript processing and/or publishing materials in the journal shall be clearly stated.

This must be:
- in a place that is easy for potential authors to find prior to submitting their manuscripts for review.

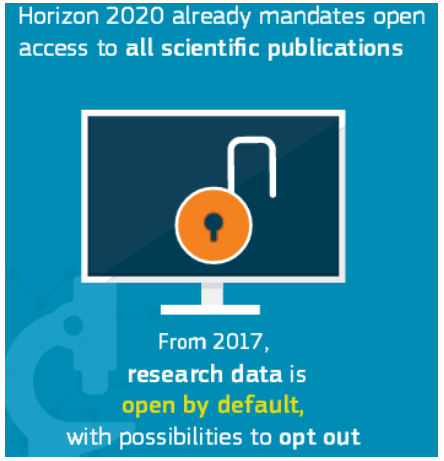
OR
- explained to authors before they begin preparing their manuscript for submission.
- if no such fees are charged that should also be stated.

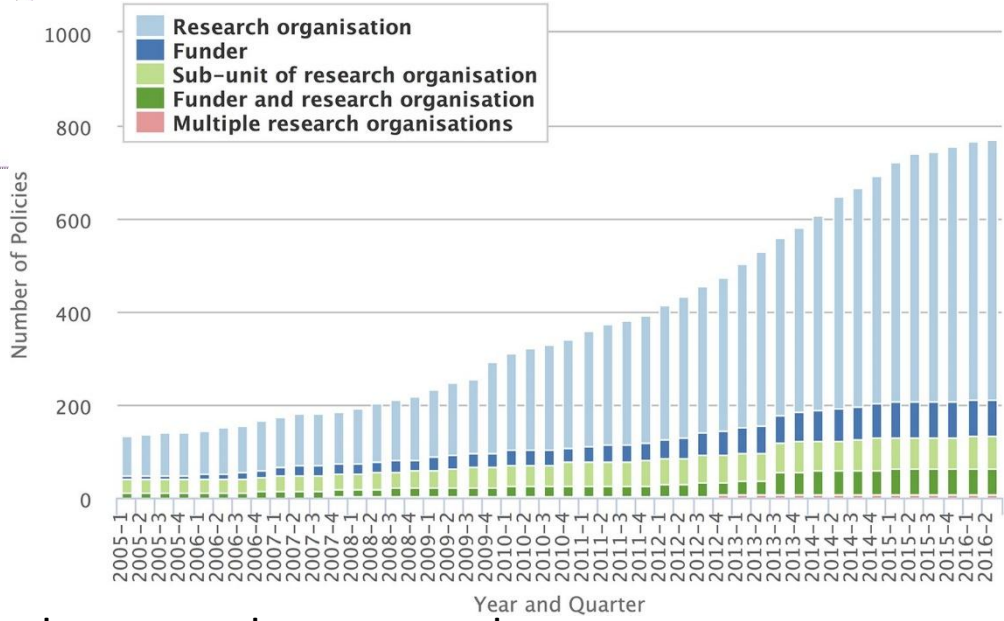
http://publicationethics.org/files/COPE_Principles_of_Transparency_Poster.pdf

Consecuencias/beneficios del acceso abierto



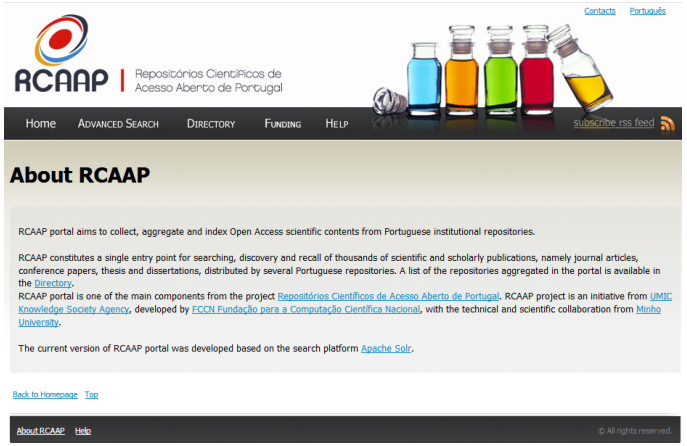
Open access articles get more citations.





McKiernan et al. (2016). How open science helps researchers succeed. eLife 2016;5:e16800 doi: [10.7554/eLife.16800](https://doi.org/10.7554/eLife.16800)

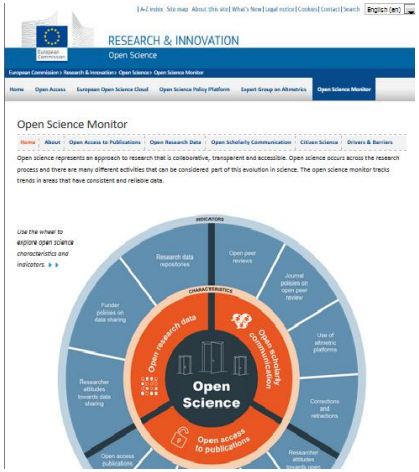
OpenAIRE

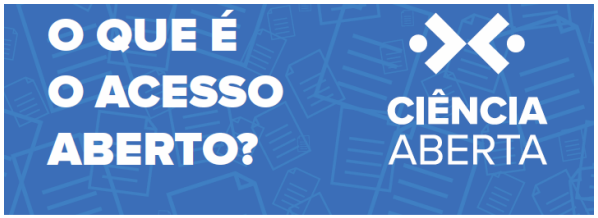


OpenDOAR

DOAJ
DIRECTORY OF
OPEN ACCESS
JOURNALS

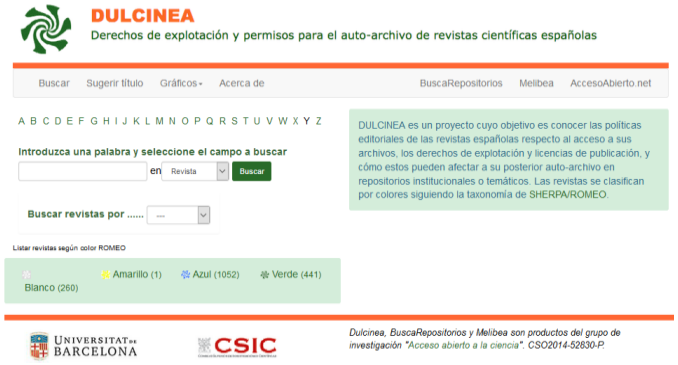
oadoi



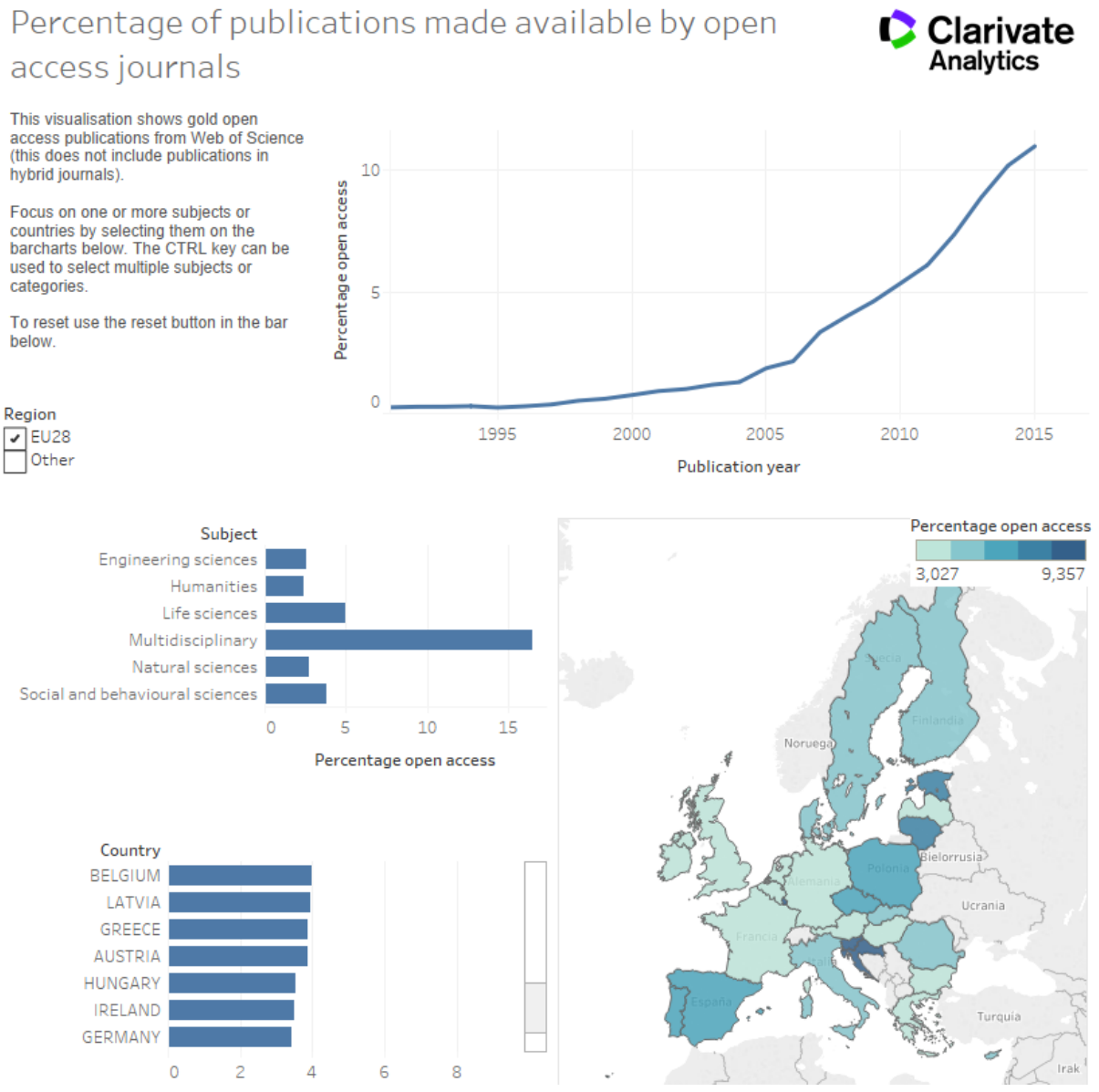


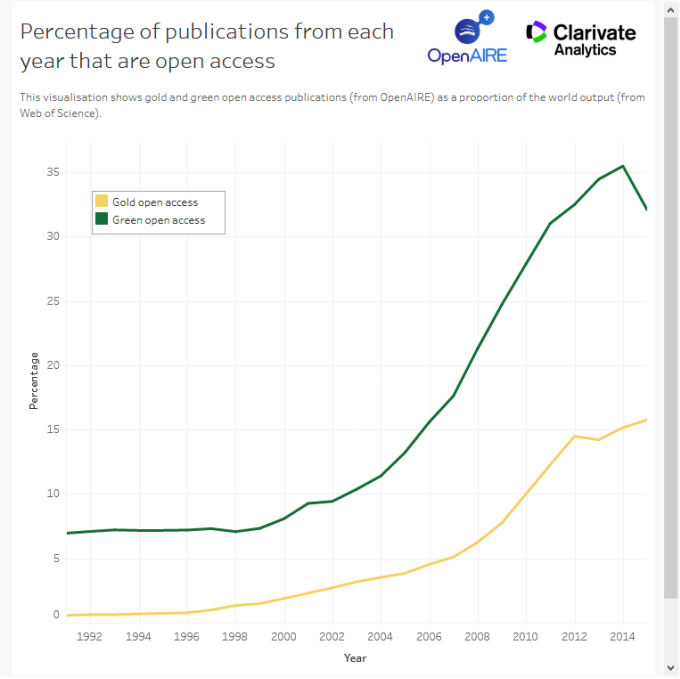
Acesso Aberto ou Open Access significa a disponibilização livre na Internet de artigos de revistas científicas revistos por pares, bem como outras publicações académicas e científicas (comunicações em conferências, teses e dissertações, relatórios técnicos, etc.) e dados de investigação.

SHERPA/RoMEO



Indicator Data

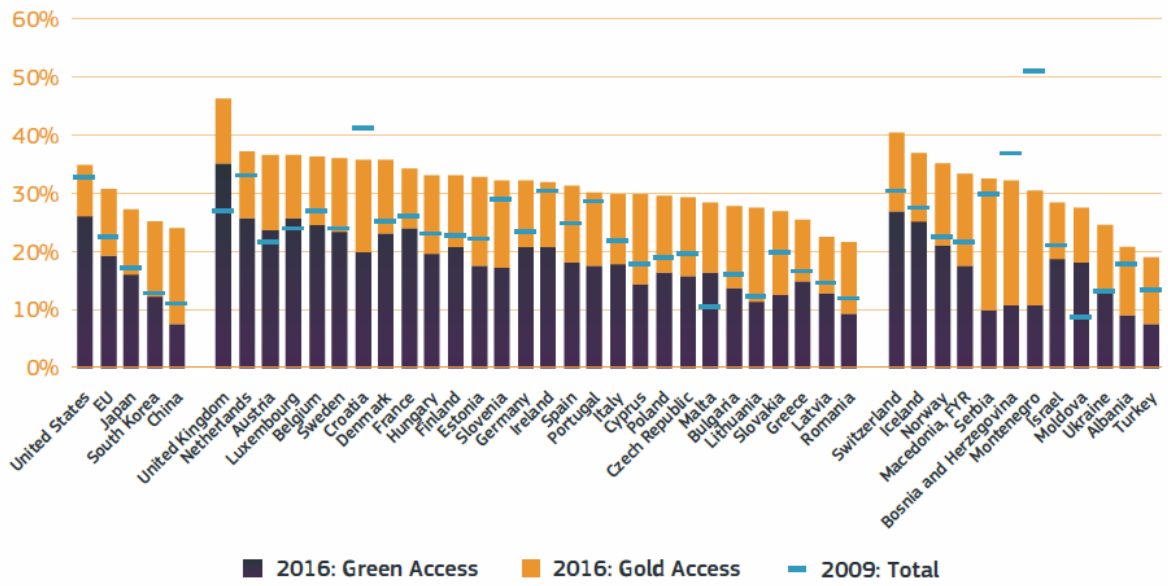


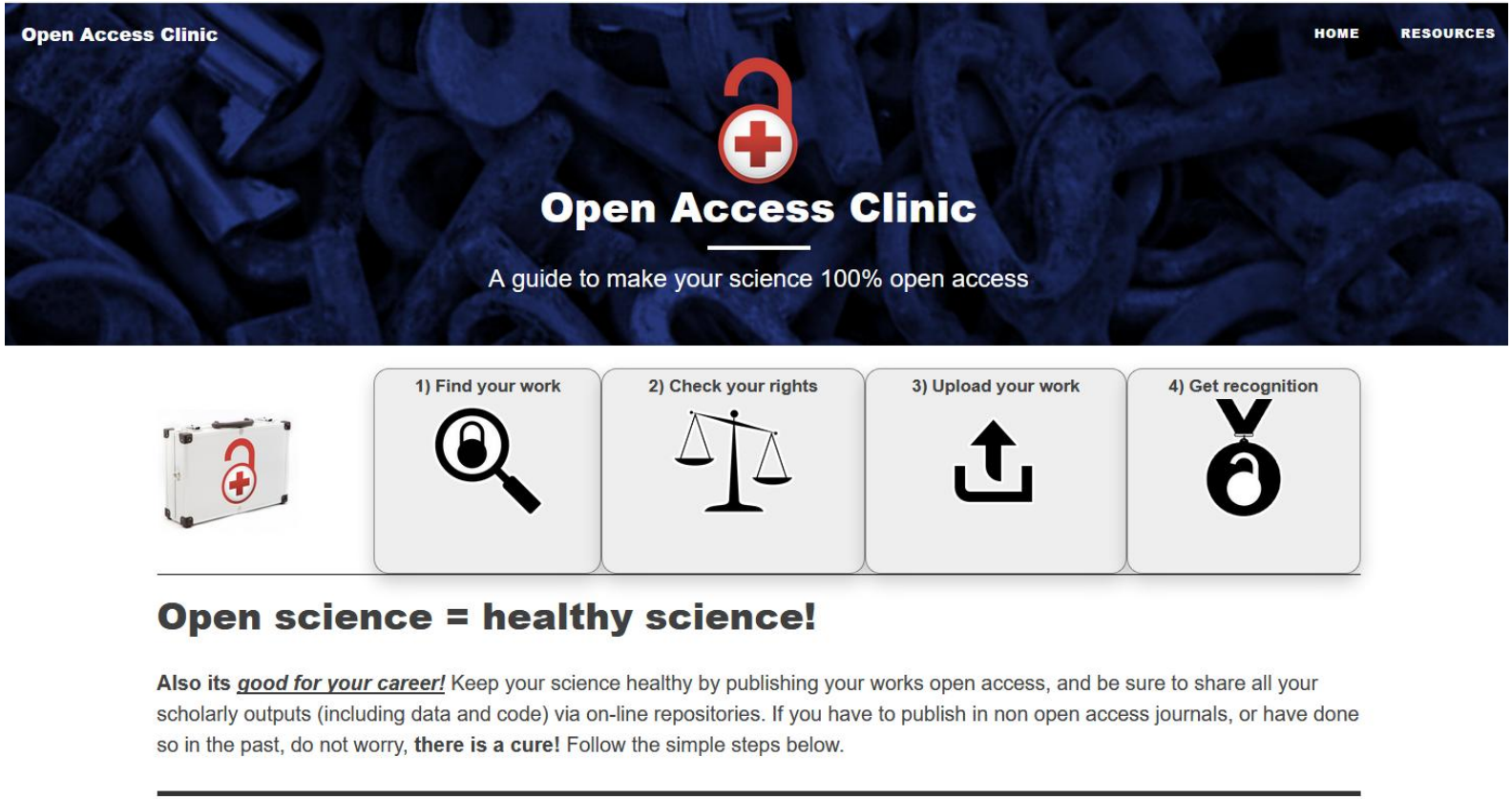


https://ec.europa.eu/research/openscience/index.cfm?pg=access&section=monitor

"European science is becoming increasingly more open-access oriented, with significant progress across all Member States"

Figure I.4-B.1 Open access scientific publications[1] with digital object identifier (DOI) as % of total scientific publications with DOI, 2009 and 2016

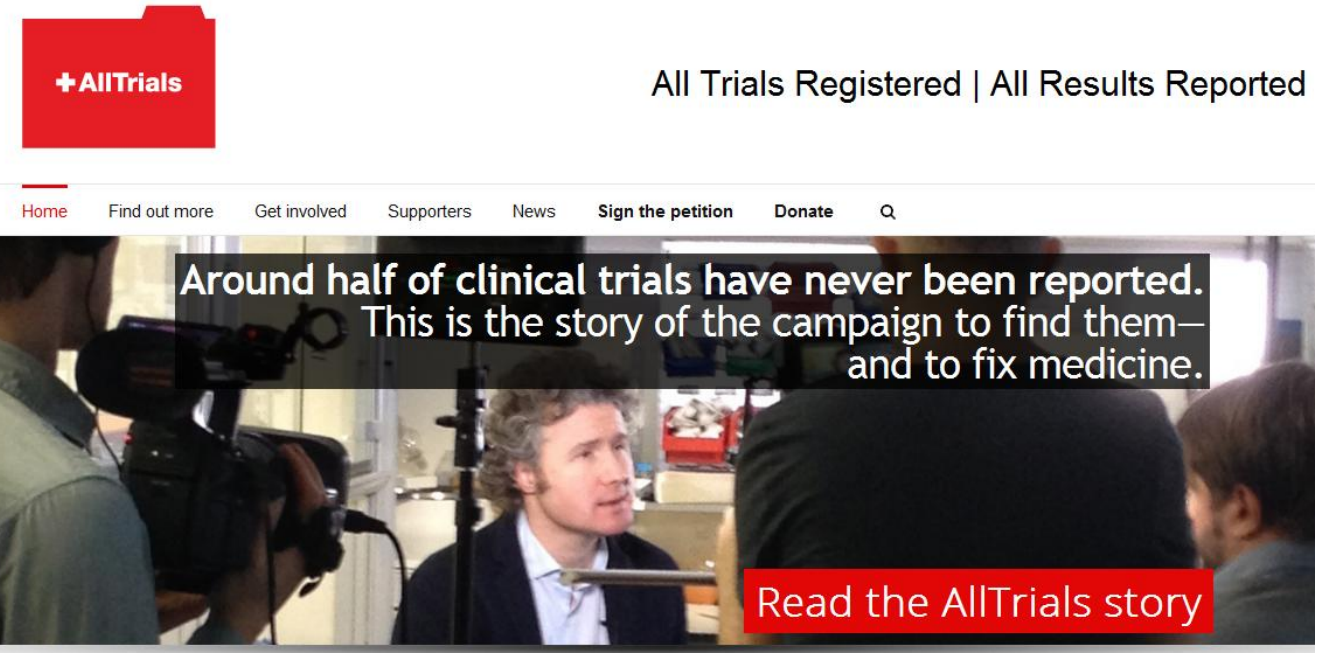


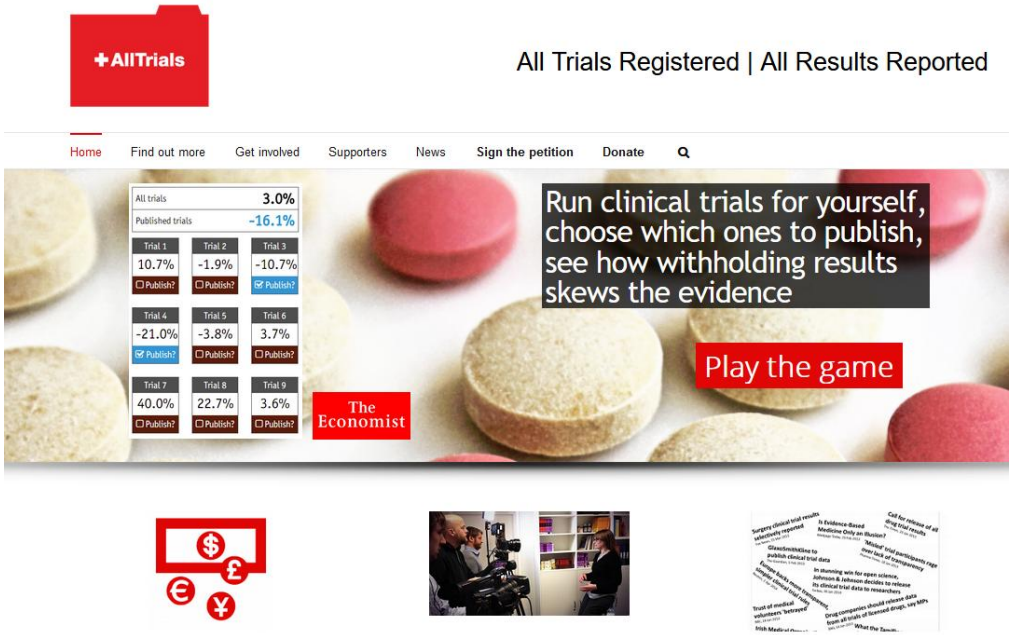


https://openaccessclinic.github.io/OA_clinic/

La importancia de compartir los protocolos (registro) y resultados de los ensayos clínicos (protocolo, datos y artículo)

- Acceso
- Transparencia
- Reproducibilidad
- Mejora del plan de trabajo (comentarios)
- La descripción no tienen limitaciones de espacio (extensión ilimitada)
- Documento citable, por lo tanto “reconocible”
- …….


+AllTrials
All Trials Registered | All Results Reported
Home
Find out more
Get involved
Supporters
News
Sign the petition
Donate
Around half of clinical trials have never been reported.
This is the story of the campaign to find them—
and to fix medicine.
Read the AllTrials story


+AllTrials
All Trials Registered | All Results Reported
Home
Find out more
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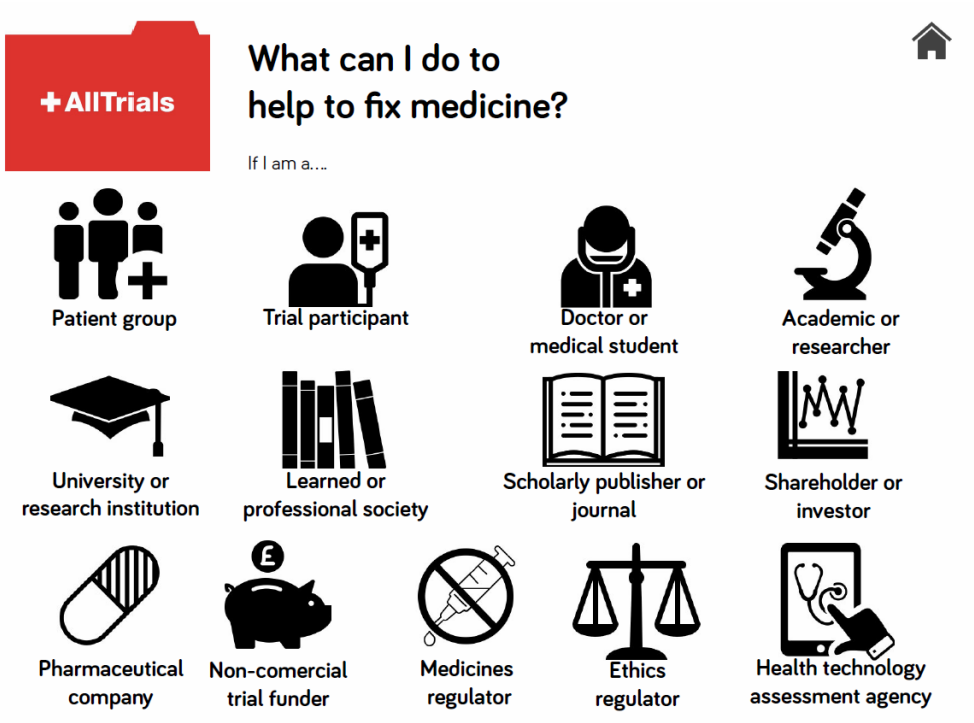
Supporters
News
Sign the petition
Donate
All trials 3.0%
Published trials -16.1%
Trial 1 10.7% Publish?
Trial 2 -1.9% Publish?
Trial 3 -10.7% Publish?
Trial 4 -21.0% Publish?
Trial 5 -3.8% Publish?
Trial 6 3.7% Publish?
Trial 7 40.0% Publish?
Trial 8 22.7% Publish?
Trial 9 3.6% Publish?
The Economist
Run clinical trials for yourself, choose which ones to publish, see how withholding results skews the evidence
Play the game

A roadmap to clinical trial transparency

http://www.alltrials.net/news/roadmap/



AllTrials campaigns for all clinical trials - past, present and future - to be registered, and their methods and results to be fully reported.

1. Trial registration. All clinical trials should be registered, with a full trial protocol, before the first participant is recruited.

2. Results posting. A summary of results, including information on the primary and any secondary outcomes measured and statistical analysis, should be posted where a trial was registered within one year of completion of a trial.

3. Trial reports. All trial reports (Clinical Study Reports or their equivalent in non-commercial settings) should be posted online in full, with only minimal redactions..

Education Life & Career Practice Management Delivering Care About Us

AMA Joins AllTrials Campaign for Clinical Trial Transparency

For immediate release: Mar 17, 2016

Today the American Medical Association (AMA) joins more than 640 patient advocacy groups, professional societies, medical organizations and thousands of patients worldwide in supporting the global campaign for clinical trial registration and reporting led by AllTrials.

"The AMA strongly supports improving the timeliness and accessibility of clinical trial data to reduce the duplication of research and help inform future research—ultimately improving health outcomes for patients," said AMA President Steven. J. Stack. "The AMA is pleased to join the AllTrials initiative to continue efforts aimed at ensuring open access to clinical trial data for physicians, researchers and patients."

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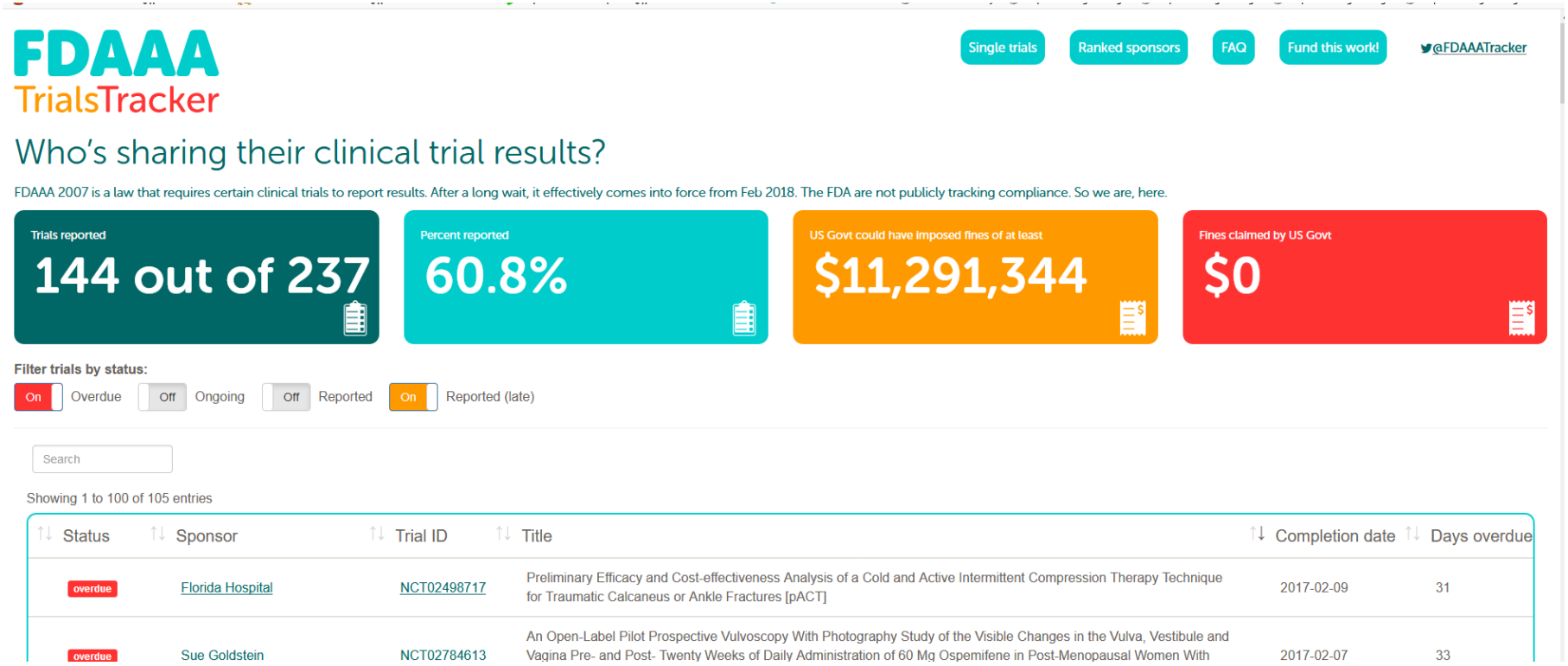
Recomienda a los editores de revistas médicas que requieran el registro de los ensayos clínicos como condición para poder considerar un trabajo para su publicación

https://opentrials.net/

Food and Drug Administration Amendments Act (FDAAA) of 2007

http://fdaaa.trialstracker.net/



World Health Organization

Health topics | Data | Media centre | Publications | Countries | Programmes | Governance | About WHO | Search

International Clinical Trials Registry Platform (ICTRP)

- International Clinical Trials Registry Platform
- About
- Registry Network
- Search portal
- Unambiguous trial identification
- Reporting of findings
- News and events
- Publications
- Clinical trials in children

Joint statement on public disclosure of results from clinical trials

Introduction

Download as PDF (including footnotes) pdf, 617kb

The current 2013 Declaration of Helsinki states that "Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject." and that "Researchers have a duty to make publicly available the results of their research .... Negative and inconclusive as well as positive results must be published or otherwise made publicly available". In addition to the ethical imperative, poor allocation of resources for product development and financing of available interventions, and suboptimal regulatory and public health recommendations may occur where decisions are based on only a subset of all completed clinical trials.

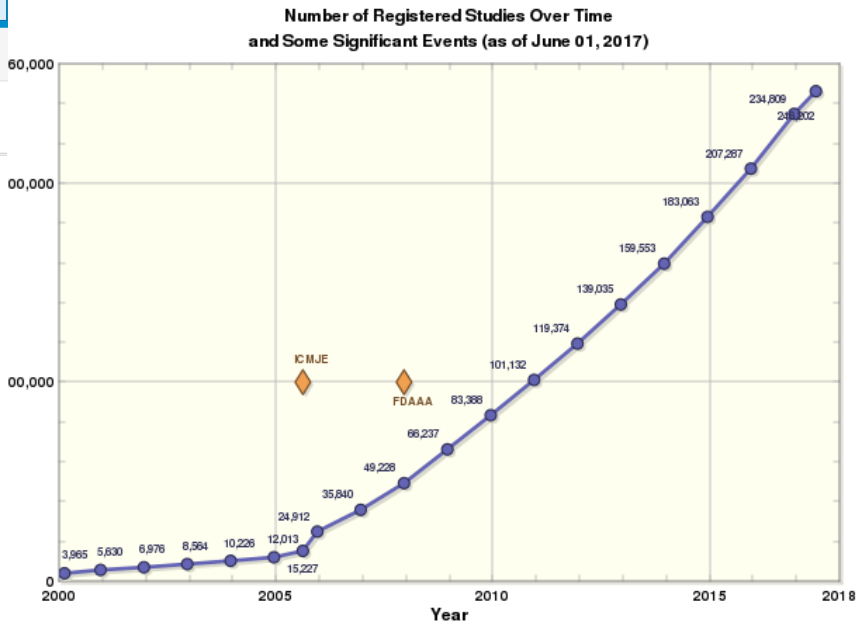
The signatories of this joint statement affirm that the prospective registration and timely public disclosure of results from all clinical trials is of critical scientific and ethical importance. Furthermore timely results disclosure reduces waste in research, increases value and efficiency in use of funds and reduces reporting bias, which should lead to better decision-making in health.

Signatories on 18 May 2017

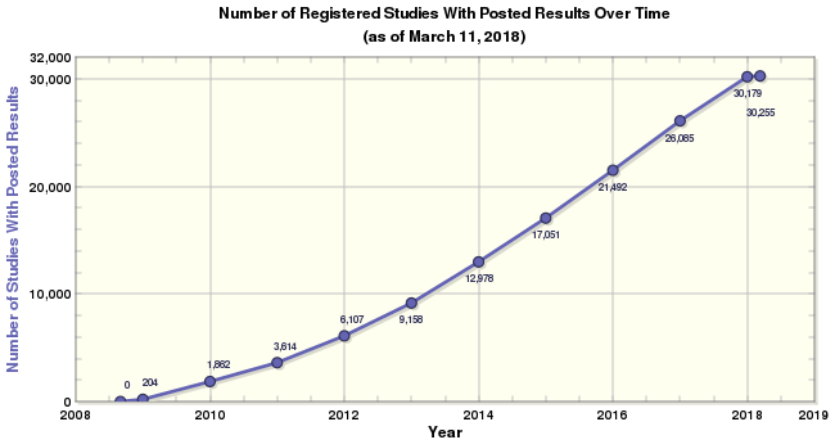
1. European Commission for Horizon 2020 Societal Challenge Health Demographic Change and Wellbeing (joined on 27 October 2017)
2. EDCTP (joined on 5 July 2017)
3. Indian Council of Medical Research
4. Inserm
5. Research Council of Norway
6. UK Department for International Development (DFID) (joined on 31 May 2017)
7. UK Medical Research Council
8. UK National Institute of Health Research (joined on 8 August 2017)
9. ZonMw (joined on 10 July 2017)
10. Aeras (joined on 13 June 2017)
11. CEPI
12. Drugs for Neglected Diseases Initiative (DNDi)
13. Epicentre
14. FIND (joined on 26 May 2017)
15. Global Alliance for TB Drug Development (TB Alliance)

1. Introduction
2. Proposed common elements of agencies' policies on results reporting
3. Quotes from signatories

http://www.who.int/ictrp/results/jointstatement/en/



e: https://ClinicalTrials.gov

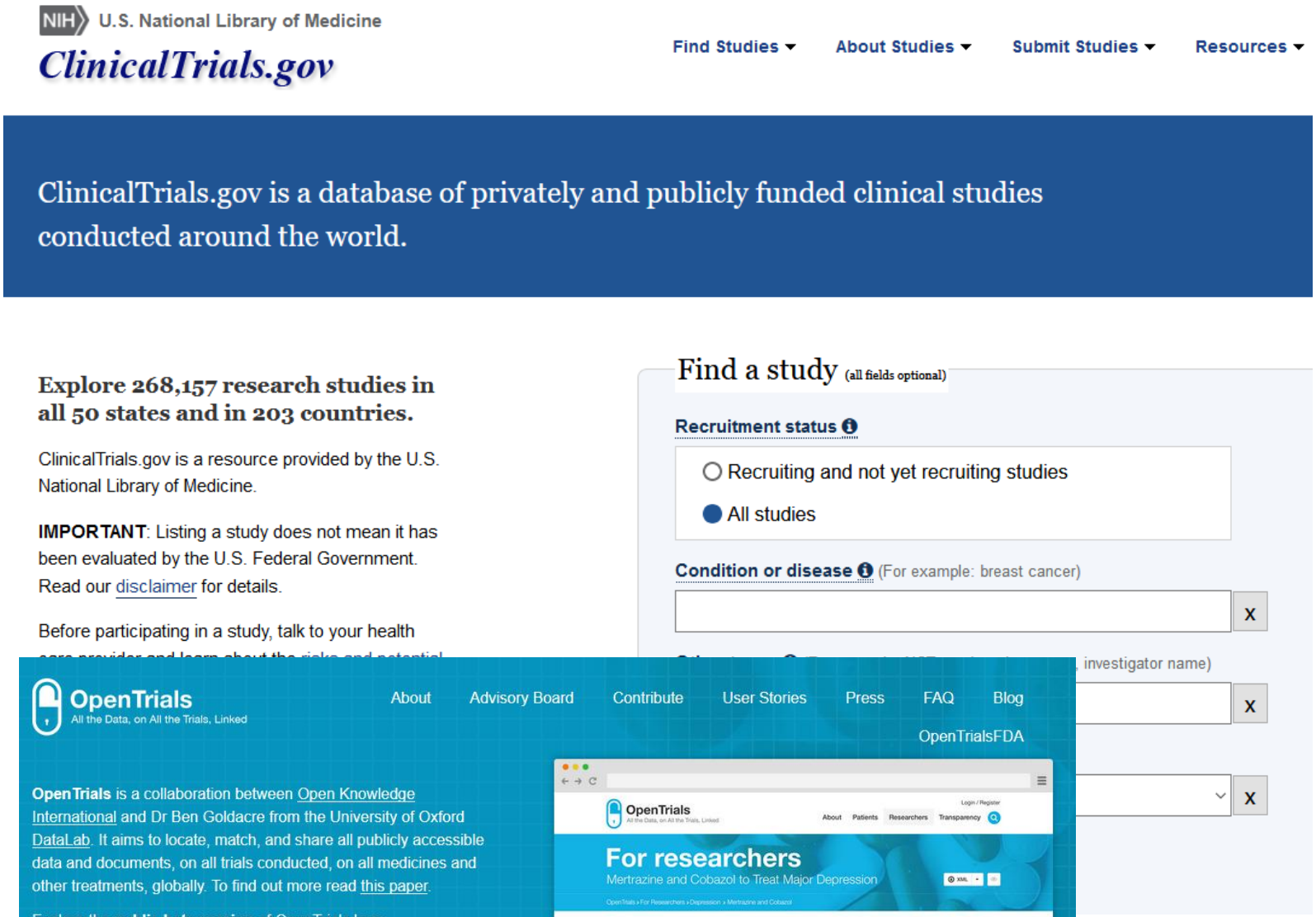


Source: https://ClinicalTrials.gov

The signatories of this joint statement affirm that the prospective registration and timely public disclosure of results from all clinical trials is of critical scientific and ethical importance. Furthermore ***timely results disclosure reduces waste in research, increases value and efficiency in use of funds and reduces reporting bias, which should lead to better decision-making in health.***

https://clinicaltrials.gov/ct2/resources/trends

https://clinicaltrials.gov/



https://opentrials.net/

https://www.clinicaltrialsregister.eu

EU Clinical Trials Register

Home & Search | Joining a trial | Contacts | About

About the EU Clinical Trials Register

The EU Clinical Trials Register contains information on interventional clinical trials on medicines conducted in the European Union (EU), or the European Economic Area (EEA) which started after 1 May 2004.

Clinical trials conducted outside the EU/EEA are included if:

- they form part of a paediatric investigation plan (PIP), or:
- they are sponsored by a marketing authorisation holder, and involve the use of a medicine in the paediatric population as part of an EU marketing authorisation.

The Register also provides information about older paediatric trials covered by an EU marketing authorisation.

The Register enables you to search for information in the EudraCT database. This is the database used by national medicines regulators for data related to clinical trial protocols. The data on the results of these trials are entered into the database by the sponsors themselves and are published in this Register once the sponsors have validated the data.

The EU clinical trials register has been a primary registry in the World Health Organization (WHO's) Registry Network since September 2011 and is a WHO Registry Network data provider. It is also available on the WHO International Clinical Trials Registry Platform.

In this Register, you are able to:

- view the description of phase II to phase IV adult clinical trials where the investigator sites are in the EU/EEA;
- view the description of any paediatric clinical trial with investigator sites in the EU/EEA;
- view the description of any paediatric clinical trial that is sponsored by a marketing authorisation holder and involves the use of a medicinal product covered by an EU marketing authorisation in the paediatric population including trials conducted outside the EU / EEA;
- view the description of any trials which form part of an agreed paediatric investigation plan (PIP) including those where the investigator sites are outside the EU/EEA;
- view the summary results of the the clinical trials mentioned above;
- view the summary results (with a reduced set of data fields) of paediatric trials completed by 26 January 2007 covered by an EU marketing authorisation;
- download up to 50 results (per request) in a text file (.txt).

http://www.who.int/ictrp/en/

World Health Organization

Health topics | Data | Media centre | Publications | Countries | Programmes | Governance | About WHO | Search

International Clinical Trials Registry Platform (ICTRP)

- International Clinical Trials Registry Platform
- About
- Registry Network
- Search portal
- Unambiguous trial identification
- Reporting of findings
- News and events
- Publications
- Clinical trials in children

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. This will improve research transparency and will ultimately strengthen the validity and value of the scientific evidence base.

WHO/P. Virot

The registration of all interventional trials is a scientific, ethical and moral responsibility.

What is a clinical trial?

For the purposes of registration, a clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials may also be referred to as interventional trials. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc. This definition includes Phase I to Phase IV trials.

What is trial registration?

WHO regards trial registration as the publication of an internationally-agreed set of information about the design, conduct and administration of clinical trials. These details are published on a publicly-accessible website managed by a registry conforming to WHO standards.

Trial Registration

Why is trial registration important?
How to register a trial
Organizations with policies on clinical trial registration
What is the difference between a clinical trials register and registry?
The Universal Trial Number (UTN)

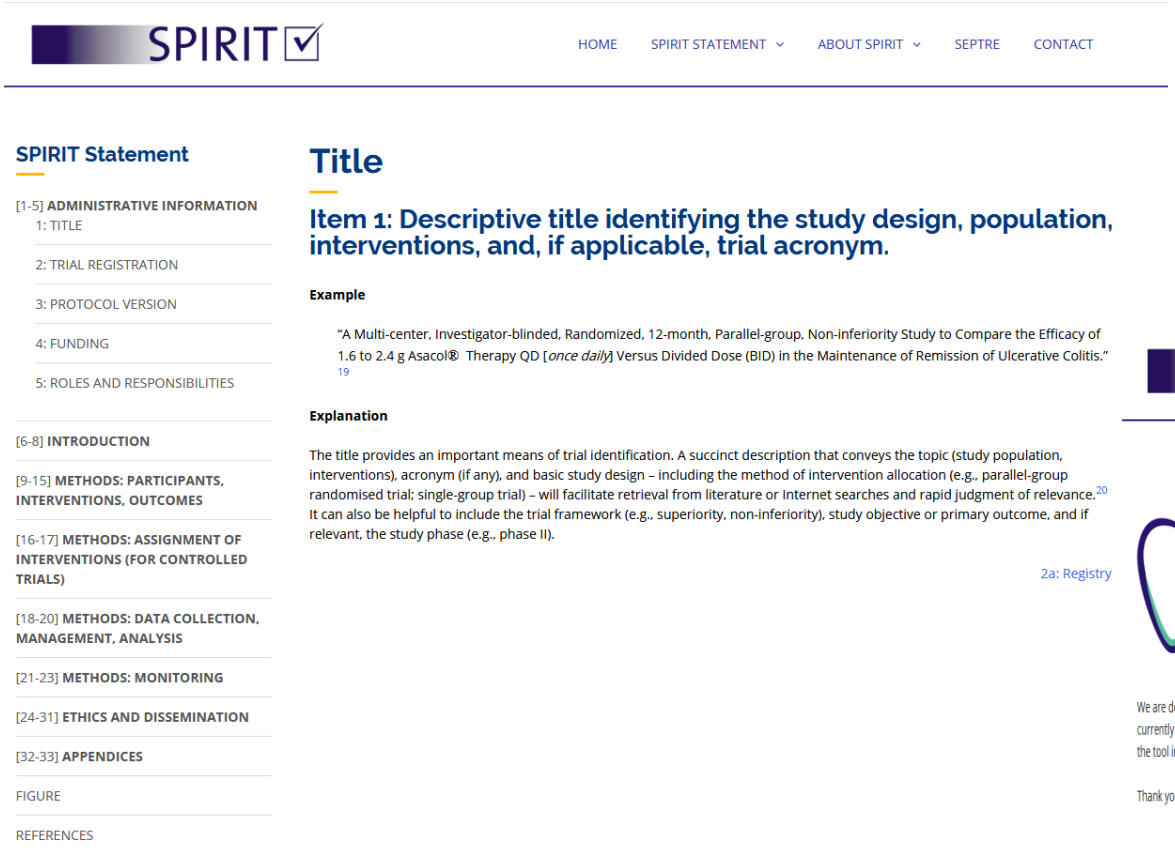
ICTRP

Search for Trials

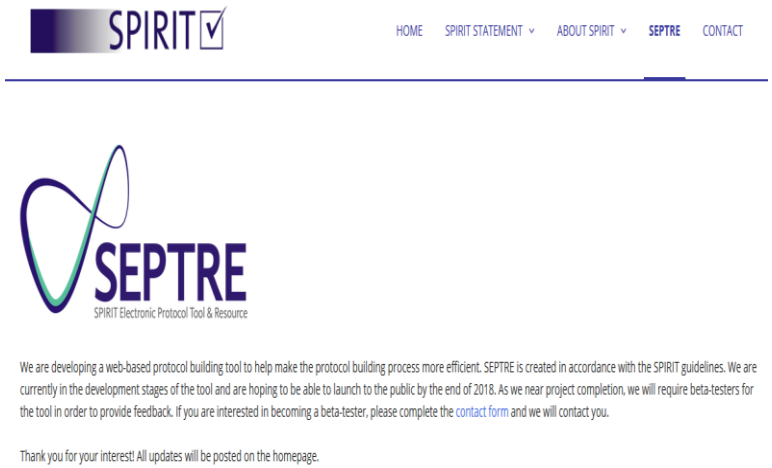
List By Health Topics
List By Countries
List By Regions/Countries

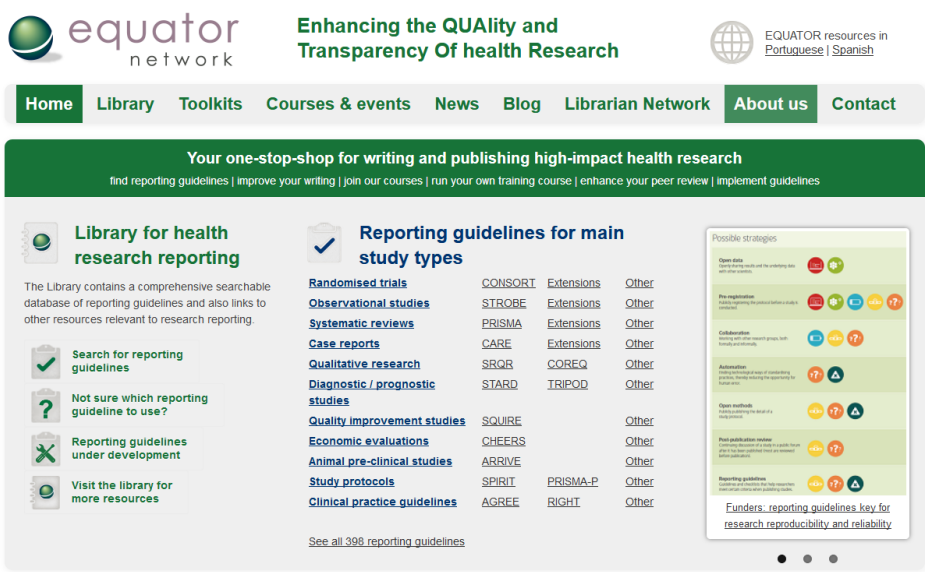
Useful Resources

International Standards for Clinical Trial Registries
ICTRP FAQ
ICTRP Glossary
ICTRP Brochure
Acknowledgements
Queries & Comments



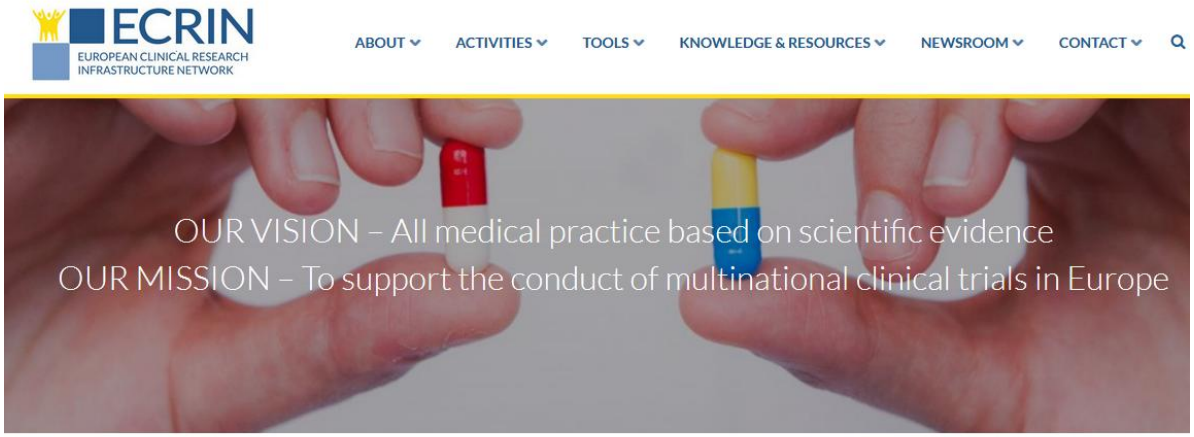
http://www.spirit-statement.org/implementation-tools/





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

ECRIN is a public, non-profit organisation that links scientific partners and networks across Europe to facilitate multinational clinical research. We provide sponsors and investigators with advice, management services and tools to overcome hurdles to multinational trials and enhance collaboration.



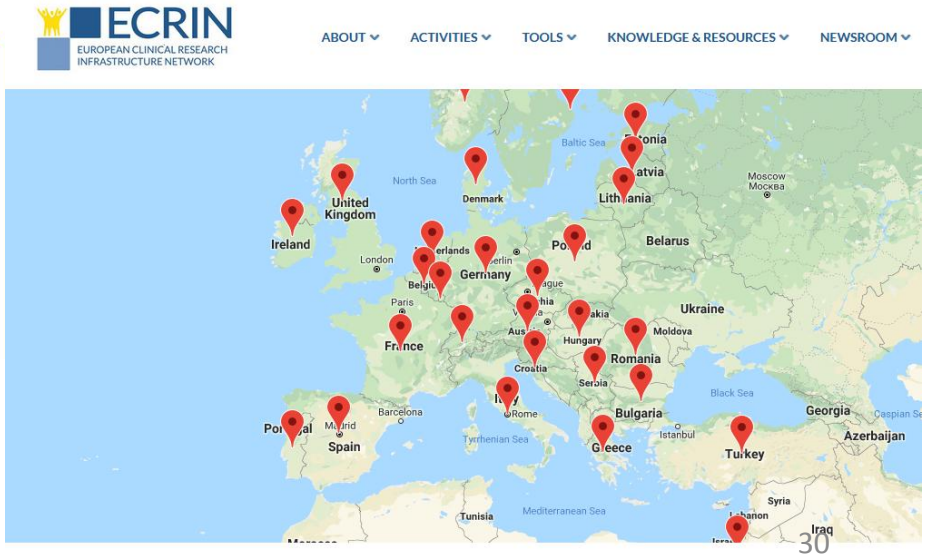
WHO WE ARE

We are a not-for-profit organisation that supports multinational clinical trials

The European Clinical Research Infrastructure Network (ECRIN) is a not-for-profit intergovernmental organisation that supports the conduct of multinational clinical trials in Europe. As of 2013, ECRIN has the legal status of a European Research Infrastructure Consortium (ERIC).

Based in Paris, we work with European Correspondents across Europe, national networks of clinical trial units (CTUs), as well as numerous European and international stakeholders involved in clinical research.

Learn how our Core Team collaborates with European Correspondents and national partners in our Member and Observer Countries.



ECRIN-SUPPORTED TRIALS

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000629.jsp&mid=WC0b01ac05808768df

Obrigada!

(rmelero@iata.csic.es)