



XIII Jornadas APDIS

Bibliotecas da Saúde
Da Ciência Aberta à Investigação
e Prática Clínica

14 - 16 MARÇO 2018

ESTeSL - Lisboa

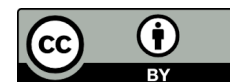


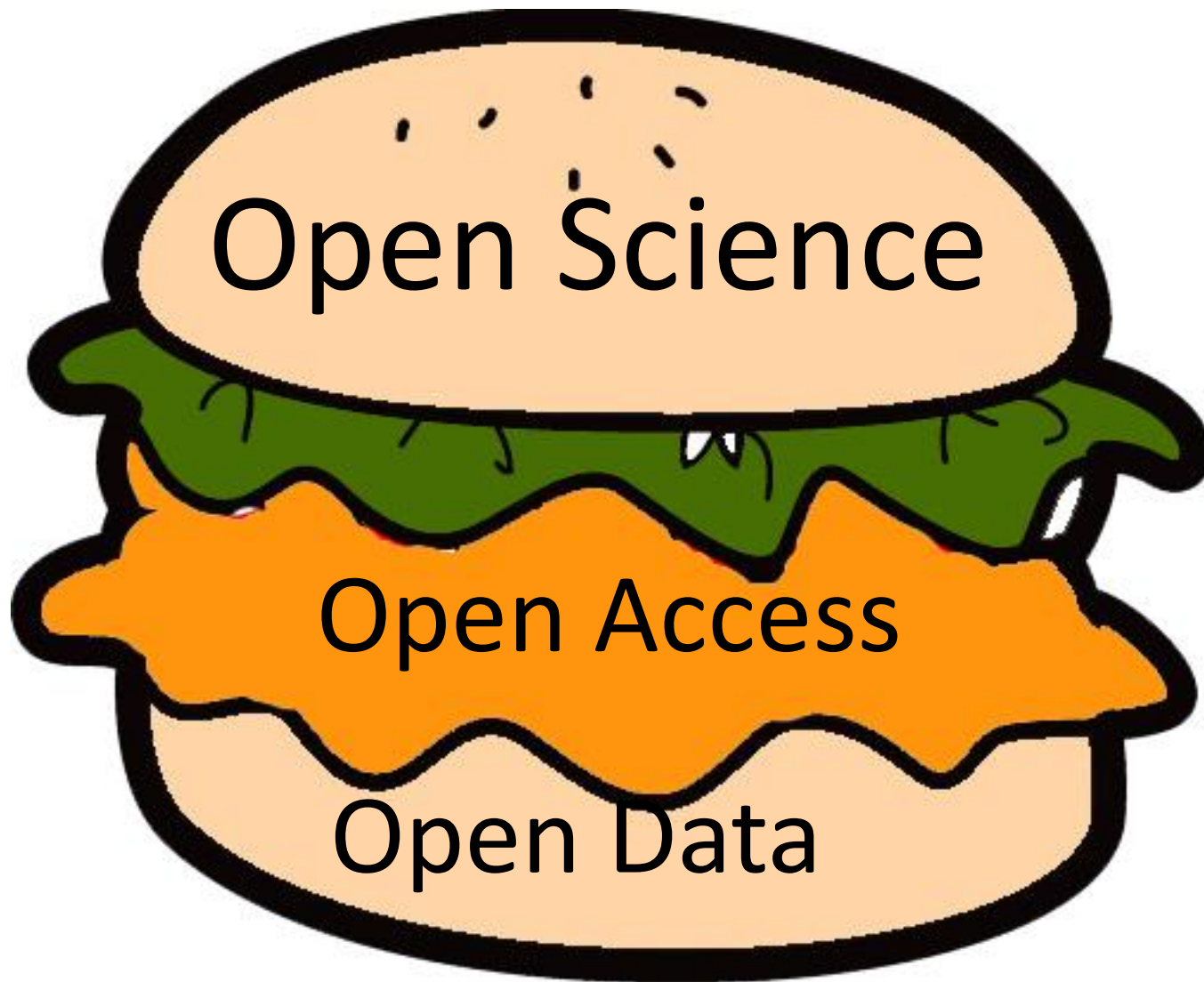
O acesso aberto é bom para a saúde
El acceso abierto es bueno para la salud

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CONSEJO SUPERIOR DE INVESTIGACIONES CIENTÍFICAS

Remedios Melero

 **FOSTER**





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



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

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00:38

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Pago por publicar (APCs)



Researcher decides
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Immediate open access
(via publisher)

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Self-archive in a
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GREEN OA ROUTE

IF OPTION EXISTS
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Immediate open access
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and SUBMIT TO A JOURNAL



IN MOST CASES*



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Journal Selector



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— Open access	?

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

The HowOpenisit? Open Access Spectrum guide illustrates the continuum from more open to less open.

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

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OPEN, RE-USABLE, SUSTAINABLE

<https://oa2020.org/>



VISION

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




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<https://fairoa.org/>

The Fair Open Access Principles

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- 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



The Transparency and Openness Promotion Guidelines
are a community-driven effort to align scientific ideals
with actual practices.

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

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.

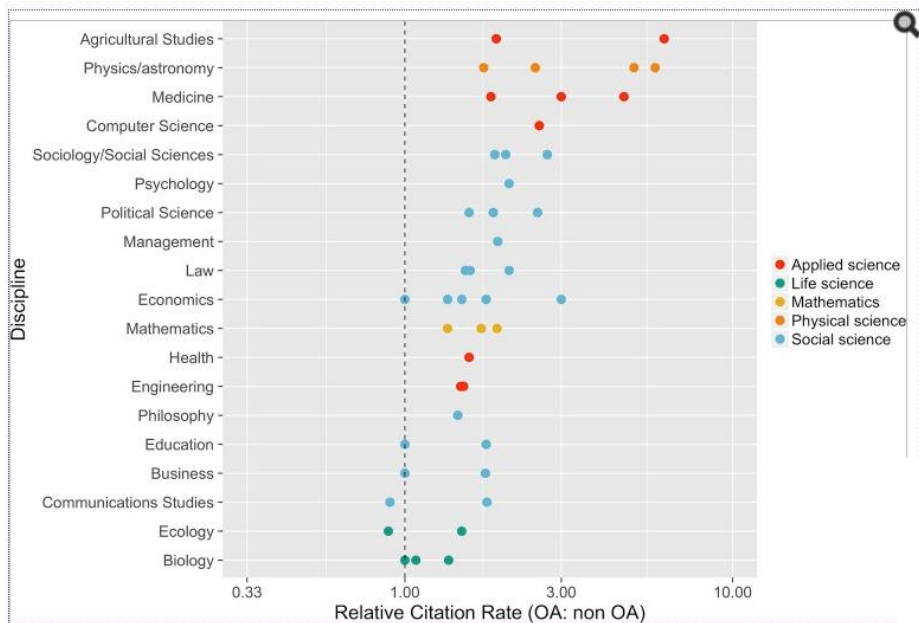


WEBSITE	NAME OF JOURNAL	PEER REVIEW PROCESS	OWNERSHIP AND MANAGEMENT
 <p>A Journal's website, including the text that it contains, shall demonstrate that care has been taken to ensure high ethical and professional standards.</p> <p>It should:</p> <ul style="list-style-type: none"> – contain an 'Aims & 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). <p>It must not:</p> <ul style="list-style-type: none"> – contain information that might mislead readers or authors. – attempt to mimic another journal/publisher's site. 	 <p>The Journal name shall be unique. It must not:</p> <ul style="list-style-type: none"> – be one that is easily confused with another journal. – mislead potential authors and readers about the Journal's origin or association with other journals. 	 <p>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.</p> <p>The journal's website should:</p> <ul style="list-style-type: none"> – clearly describe this process, as well as any policies related to the journal's peer review procedures including the method of peer review used. <p>The journal's website should not:</p> <ul style="list-style-type: none"> – guarantee manuscript acceptance or very short peer review times. 	 <p>Information about the ownership and/or management of a journal shall be clearly indicated on the journal's website.</p> <p>Publishers should not:</p> <ul style="list-style-type: none"> – use organizational or journal names that would mislead potential authors and editors about the nature of the journal's owner.
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 <p>Journals shall have editorial boards or other governing bodies whose members are recognized experts in the subject areas included within the journal's scope.</p> <p>The journal's website should:</p> <ul style="list-style-type: none"> – show full names and affiliations of the journal's editorial board or other governing body. 	 <p>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.</p>	 <p>The policy for copyright shall be clearly stated in the author guidelines and the copyright holder named on all published articles.</p> <p>The journal's website should:</p> <ul style="list-style-type: none"> – show licensing information clearly described in guidelines. <p>Licensing terms shall be indicated on all published articles, both HTML and PDFs.</p> <p>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.</p>	 <p>Any fees or charges that are required for manuscript processing and/or publishing materials in the journal shall be clearly stated.</p> <p>This must be:</p> <ul style="list-style-type: none"> – in a place that is easy for potential authors to find prior to submitting their manuscripts for review. <p>OR</p> <ul style="list-style-type: none"> – explained to authors before they begin preparing their manuscript for submission. – if no such fees are charged that should also be stated.



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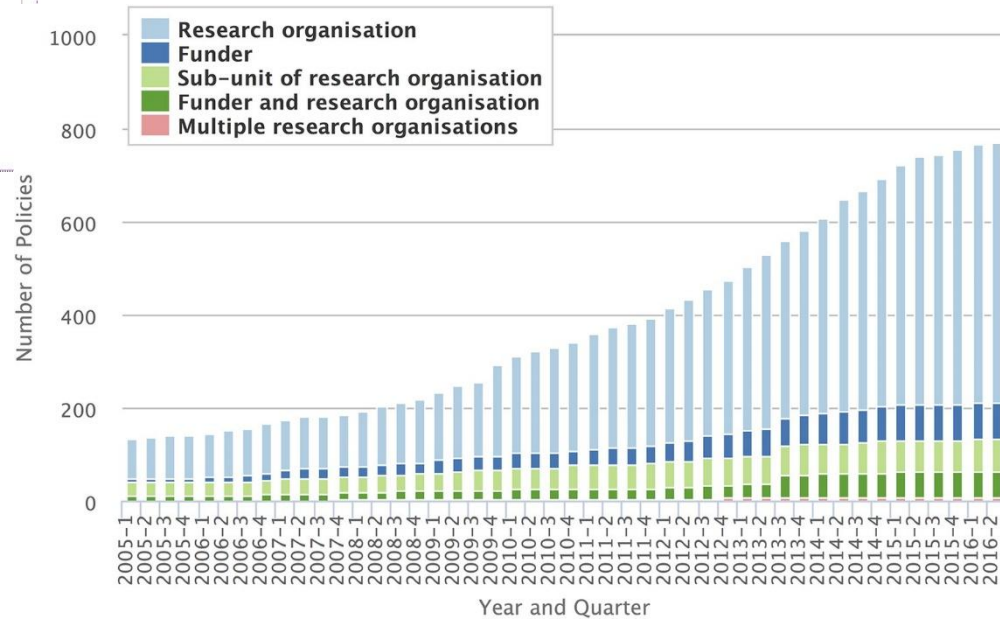


Open access articles get more citations.

Horizon 2020 already mandates open access to all scientific publications



From 2017,
research data is
open by default,
with possibilities to opt out



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)

Open Calls for Innovation



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About RCAAP

RCAAP portal aims to collect, aggregate and index Open Access scientific contents from Portuguese institutional repositories.

RCAAP constitutes a single entry point for searching, discovery and recall of thousands of scientific and scholarly publications, namely journal articles, conference papers, theses and dissertations, distributed by several Portuguese repositories. A list of the repositories aggregated in the portal is available in the [Directory](#).

RCAAP portal is one of the main components from the project [Repositórios Científicos de Acesso Aberto de Portugal](#). RCAAP project is an initiative from [IMIC Knowledge Society Agency](#), developed by [ECCN Fundação para a Computação Científica Nacional](#), with the technical and scientific collaboration from [Minho University](#).

The current version of RCAAP portal was developed based on the search platform [Apache Solr](#).

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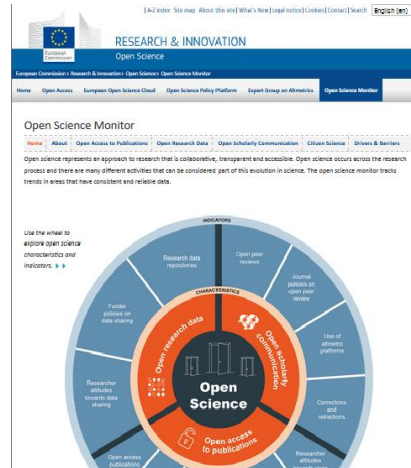
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JOURNALS

oadoi



O QUE É O ACESSO ABERTO?

CIÊNCIA ABERTA

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

VANTAGENS DO ACESSO ABERTO



Promove e acelera o
progresso da investigação
e da ciência



Aumenta a visibilidade,
o acesso, a utilização e o
impacto dos resultados
de investigação



Melhora a monitorização,
avaliação e gestão da
atividade científica



SHERPA/ROMEO



DULCINEA

Derechos de explotación y permisos para el auto-archivo de revistas científicas españolas

[Buscar](#) [Sugerir título](#) [Gráficos](#) [Acerca de](#) [BuscaRepositorios](#) [Melbea](#) [AccesoAbierto.net](#)

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

Introduzca una palabra y seleccione el campo a buscar

en [Revista](#) [Buscar](#)

Buscar revistas por [...](#)

Listar revistas según color ROMEO

[Blanco \(269\)](#) [Amarillo \(1\)](#) [Azul \(1052\)](#) [Verde \(441\)](#)

DULCINEA es un proyecto cuyo objetivo es conocer las políticas editoriales de las revistas españolas respecto al acceso a sus archivos, los derechos de explotación y licencias de publicación, y cómo estos pueden afectar a su posterior auto-archivo en repositorios institucionales o temáticos. Las revistas se clasifican por colores siguiendo la taxonomía de SHERPAROMEO.

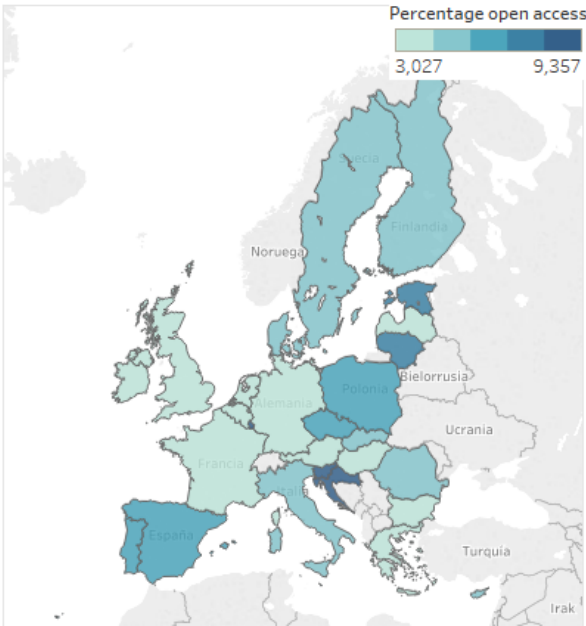
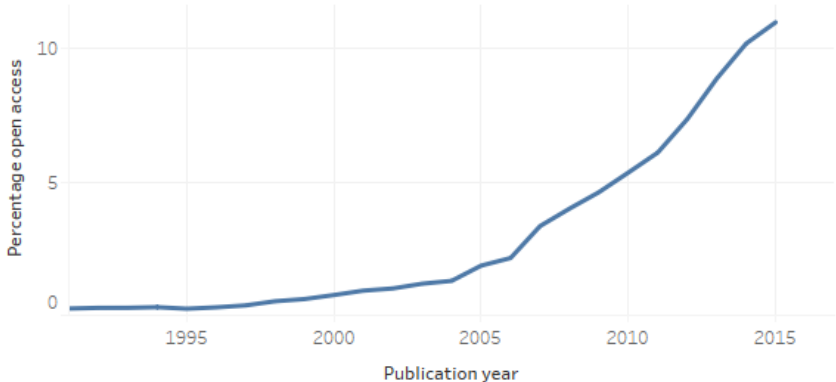
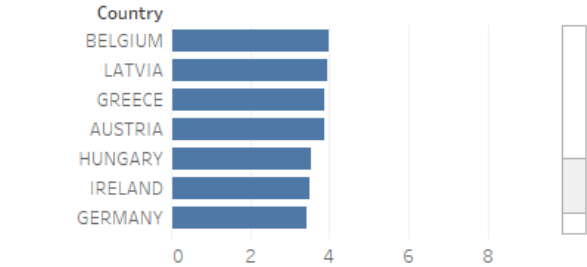
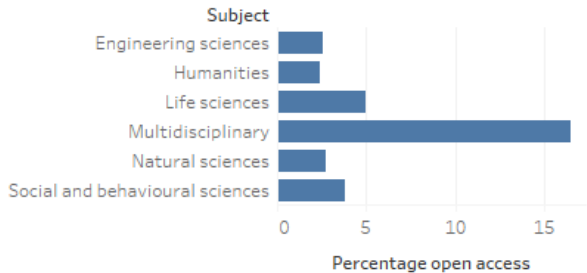
Percentage of publications made available by open access journals

This visualisation shows gold open access publications from Web of Science (this does not include publications in hybrid journals).

Focus on one or more subjects or countries by selecting them on the barcharts below. The CTRL key can be used to select multiple subjects or categories.

To reset use the reset button in the bar below.

Region
☒ EU28
☐ Other

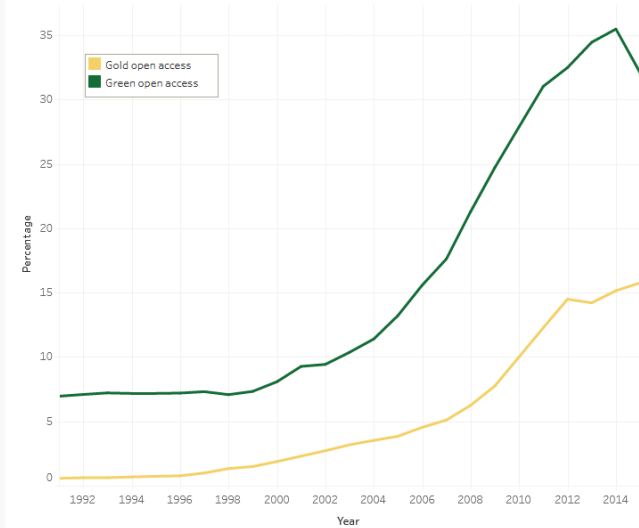


Indicator Data

Percentage of publications from each year that are open access



This visualisation shows gold and green open access publications (from OpenAIRE) as a proportion of the world output (from Web of Science).





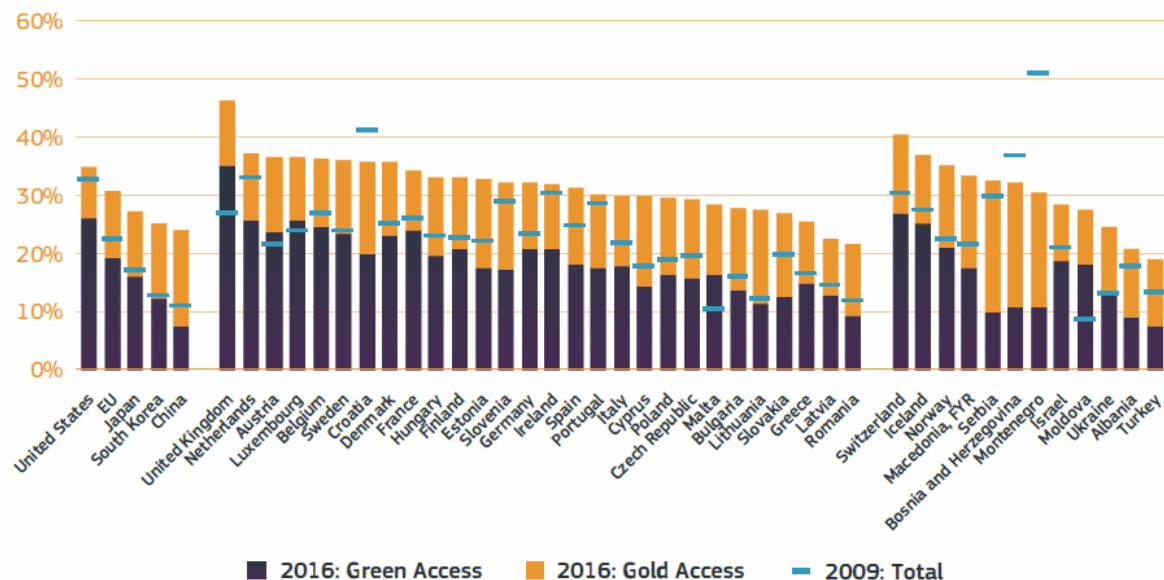
SCIENCE, RESEARCH AND INNOVATION PERFORMANCE OF THE EU 2018

Strengthening
the foundations
for Europe's future

Research and
Innovation

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

Figure I.4-B.1 Open access scientific publications¹ with digital object identifier (DOI) as % of total scientific publications with DOI, 2009 and 2016





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2) Check your rights



3) Upload your work



4) Get recognition



Open science = healthy science!

Also its good for your career! Keep your science healthy by publishing your works open access, and be sure to share all your scholarly outputs (including data and code) via on-line repositories. If you have to publish in non open access journals, or have done so in the past, do not worry, **there is a cure!** Follow the simple steps below.

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”
-

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

All trials			3.0%
Published trials			-16.1%
Trial 1	Trial 2	Trial 3	
10.7%	-1.9%	-10.7%	
<input type="checkbox"/> Publish?	<input type="checkbox"/> Publish?	<input checked="" type="checkbox"/> Publish?	
Trial 4	Trial 5	Trial 6	
-21.0%	-3.8%	3.7%	
<input checked="" type="checkbox"/> Publish?	<input type="checkbox"/> Publish?	<input type="checkbox"/> Publish?	
Trial 7	Trial 8	Trial 9	
40.0%	22.7%	3.6%	
<input type="checkbox"/> Publish?	<input type="checkbox"/> Publish?	<input type="checkbox"/> Publish?	

Run clinical trials for yourself,
choose which ones to publish,
see how withholding results
skews the evidence

Play the game

The Economist



A roadmap to clinical trial transparency

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



What can I do to help to fix medicine?

If I am a...



Patient group



Trial participant



Doctor or medical student



Academic or researcher



University or research institution



Learned or professional society



Scholarly publisher or journal



Shareholder or investor



Pharmaceutical company



Non-commercial trial funder



Medicines regulator



Ethics regulator



Health technology assessment agency

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..

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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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Clinical Trial Registration

The ICMJE's clinical trial registration policy is detailed in a series of editorials (see [Updates and Editorials](#) and [FAQs](#)).

Briefly, the ICMJE requires, and recommends that all medical journal editors require, registration of clinical trials in a public trials registry at or before the time of first patient enrollment as a condition of consideration for publication. Editors requesting inclusion of their journal on the ICMJE website [list of publications](#) that follow ICMJE guidance should recognize that the listing implies enforcement by the journal of ICMJE's trial registration policy.

The ICMJE defines a clinical trial as any research project that prospectively assigns people or a group of people to an intervention, with or without concurrent comparison or control groups, to study the cause-and-effect relationship between a health-related intervention *and* a health outcome. Health-related interventions are those used to modify a biomedical or health-related outcome; examples include drugs, surgical procedures, devices, behavioural treatments, educational programs, dietary interventions, quality improvement interventions, and process-of-care changes. Health outcomes are any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events. The ICMJE does not define the timing of first patient enrollment, but best practice dictates registration by the time of first patient consent.

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

Food and Drug Administration Amendments Act (FDAAA) of 2007

<http://fdaaa.trialstracker.net/>

FDAAA TrialsTracker

[Single trials](#)[Ranked sponsors](#)[FAQ](#)[Fund this work!](#)[@FDAATracker](#)

Who's sharing their clinical trial results?

FDAAA 2007 is a law that requires certain clinical trials to report results. After a long wait, it effectively comes into force from Feb 2018. The FDA are not publicly tracking compliance. So we are, here.

Trials reported

144 out of 237

Percent reported

60.8%

US Govt could have imposed fines of at least

\$11,291,344

Fines claimed by US Govt

\$0

Filter trials by status:

☒ On ☐ Overdue ☐ Off ☐ Ongoing ☐ Off ☐ Reported ☒ On ☐ Reported (late)

Showing 1 to 100 of 105 entries

↑↓ Status	↑↓ Sponsor	↑↓ Trial ID	↑↓ Title	↑↓ Completion date	↑↓ Days overdue
overdue	Florida Hospital	NCT02498717	Preliminary Efficacy and Cost-effectiveness Analysis of a Cold and Active Intermittent Compression Therapy Technique for Traumatic Calcaneus or Ankle Fractures [pACT]	2017-02-09	31
overdue	Sue Goldstein	NCT02784613	An Open-Label Pilot Prospective Vulvoscopy With Photography Study of the Visible Changes in the Vulva, Vestibule and Vagina Pre- and Post- Twenty Weeks of Daily Administration of 60 Mg Ospemifene in Post-Menopausal Women With	2017-02-07	33

Joint statement on public disclosure of results from clinical trials

Introduction

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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.

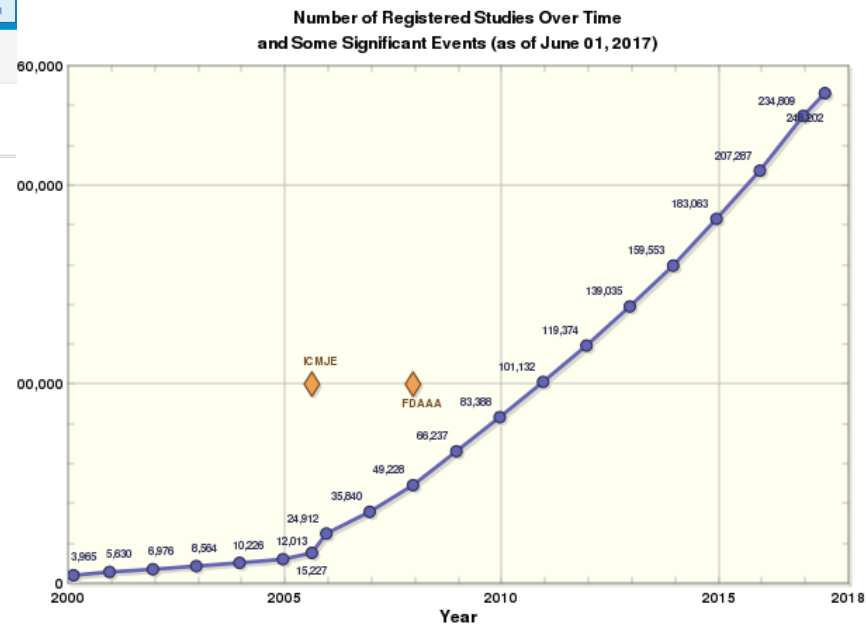
The signatories of this joint statement affirm that the prospective registration and timely public disclosure of results from all clinical trials is of critical scientific and ethical importance. Furthermore timely results disclosure reduces waste in research, increases value and efficiency in use of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

Signatories on 18 May 2017

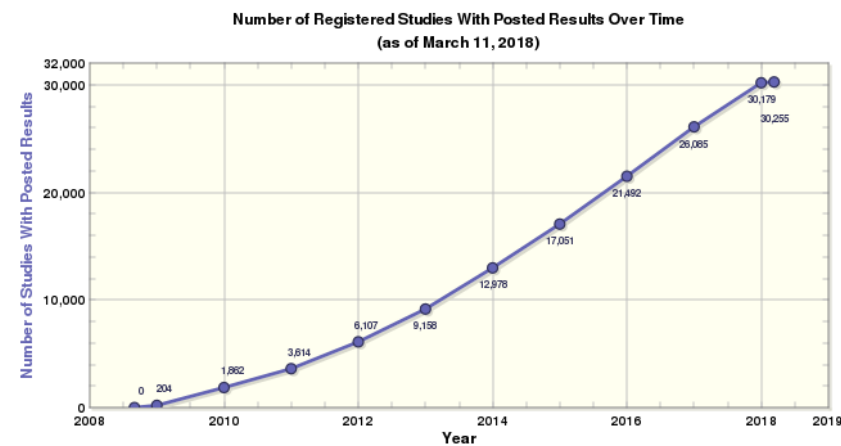
1. European Commission for Horizon 2020 Societal Challenge Health Demographic Change and Wellbeing (joined on 27 October 2017)
2. EDCTP (joined on 5 July 2017)
3. Indian Council of Medical Research
4. Inserm
5. Research Council of Norway
6. UK Department for International Development (DFID) (joined on 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)

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



Source: <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>



ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world.

Explore **268,157** research studies in all 50 states and in 203 countries.

ClinicalTrials.gov is a resource provided by the U.S. National Library of Medicine.

IMPORTANT: Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our [disclaimer](#) for details.

Before participating in a study, talk to your health care provider and learn about the risks and potential

Find a study (all fields optional)

Recruitment status ⓘ

- ☐ Recruiting and not yet recruiting studies
- ☒ All studies

Condition or disease ⓘ (For example: breast cancer)

X

investigator name)

X

X



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OpenTrialsFDA

OpenTrials is a collaboration between [Open Knowledge International](#) and Dr Ben Goldacre from the University of Oxford [DataLab](#). It aims to locate, match, and share all publicly accessible data and documents, on all trials conducted, on all medicines and other treatments, globally. To find out more read [this paper](#).

Explore the **public beta version** of OpenTrials [here](#).

Find trial by title, identifier or other keywords (e.g. "heart attack")



Advanced search

▶ Intro video

OpenTrials
All the Data, on All the Trials, Linked

About Patients Researchers Transparency

Login / Register

For researchers

Mertrazine and Cobazol to Treat Major Depression

OpenTrials » For Researchers » Depression » Mertrazine and Cobazol

Overview

Condition: Major Depression Treatment: ☒ Mertrazine, ☒ Cobazol June 2004 - March 2010

Participants Men and women Aged 18-65

Registries

ClinicalTrials.gov

BiMed Inc.

Regulatory documents

CSR

EPHR segment

Paperwork

Blank consent form

Patient information sheet

Blank case report form

<https://opentrials.net/>

<https://www.clinicaltrialsregister.eu>



EU Clinical Trials Register

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[Joining a trial](#)

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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/>



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International Clinical Trials Registry Platform (ICTRP)

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[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. Viroc

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 \(UTN\)](#)



[Search for Trials](#)

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[List By Regions/Countries](#)

Useful Resources

[International Standards for Clinical Trial Registries](#)

[ICTRP FAQ](#)

[ICTRP Glossary](#)

[ICTRP Brochure](#)

[Acknowledgements](#)

[Queries & Comments](#)

SPIRIT Statement

[1-5] ADMINISTRATIVE INFORMATION

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- 2: TRIAL REGISTRATION
- 3: PROTOCOL VERSION
- 4: FUNDING
- 5: ROLES AND RESPONSIBILITIES

[6-8] INTRODUCTION

[9-15] METHODS: PARTICIPANTS, INTERVENTIONS, OUTCOMES

[16-17] METHODS: ASSIGNMENT OF INTERVENTIONS (FOR CONTROLLED TRIALS)

[18-20] METHODS: DATA COLLECTION, MANAGEMENT, ANALYSIS

[21-23] METHODS: MONITORING

[24-31] ETHICS AND DISSEMINATION

[32-33] APPENDICES

FIGURE

REFERENCES

Title

Item 1: Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym.

Example

"A Multi-center, Investigator-blinded, Randomized, 12-month, Parallel-group, Non-inferiority Study to Compare the Efficacy of 1.6 to 2.4 g Asacol® Therapy QD [*once daily*] Versus Divided Dose (BID) in the Maintenance of Remission of Ulcerative Colitis."

Explanation

The title provides an important means of trial identification. A succinct description that conveys the topic (study population, interventions), acronym (if any), and basic study design – including the method of intervention allocation (e.g., parallel-group randomised trial; single-group trial) – will facilitate retrieval from literature or Internet searches and rapid judgment of relevance.²⁰ It can also be helpful to include the trial framework (e.g., superiority, non-inferiority), study objective or primary outcome, and if relevant, the study phase (e.g., phase II).

2a: Registry



We are developing a web-based protocol building tool to help make the protocol building process more efficient. SEPTRE is created in accordance with the SPIRIT guidelines. We are currently in the development stages of the tool and are hoping to be able to launch to the public by the end of 2018. As we near project completion, we will require beta-testers for the tool in order to provide feedback. If you are interested in becoming a beta-tester, please complete the [contact form](#) and we will contact you.

Thank you for your interest! All updates will be posted on the homepage.



Enhancing the QUALity and Transparency Of health Research



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Your one-stop-shop for writing and publishing high-impact health research

find reporting guidelines | improve your writing | join our courses | run your own training course | enhance your peer review | implement guidelines

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
-  Not sure which reporting guideline to use?
-  Reporting guidelines under development
-  Visit the library for more resources

Reporting guidelines for main study types

Randomised trials	CONSORT	Extensions	Other
Observational studies	STROBE	Extensions	Other
Systematic reviews	PRISMA	Extensions	Other
Case reports	CARE	Extensions	Other
Qualitative research	SRQR	COREQ	Other
Diagnostic / prognostic studies	STARQ	TRIPOD	Other
Quality improvement studies	SQUIRE		Other
Economic evaluations	CHEERS		Other
Animal pre-clinical studies	ARRIVE		Other
Study protocols	SPIRIT	PRISMA-P	Other
Clinical practice guidelines	AGREE	RIGHT	Other

See all 398 reporting guidelines

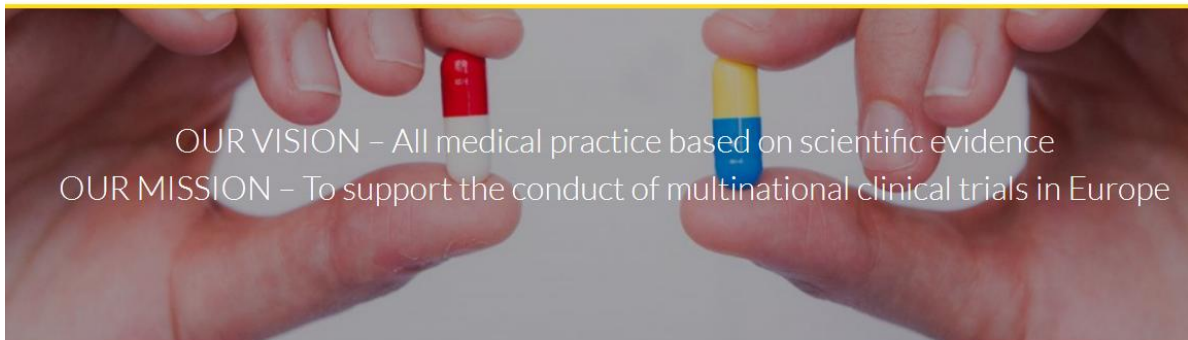


<http://www.equator-network.org/>

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.



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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.](#)



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



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Overview

▼ Research and development

Adaptive pathways

Advanced therapies

▼ Clinical trials

► Clinical trial regulation

Compassionate use

Compliance

Data on medicines (ISO IDMP standards)

Geriatric medicine

Innovation in medicines

Non-pharmaceutical products

Orphan designation

Paediatric medicines

Pharmacovigilance

PRIME: priority medicines

► Home ► Human regulatory ► Research and development ► Clinical trials ► Clinical trial regulation

Clinical Trial Regulation

The way clinical trials are conducted in the European Union (EU) will undergo a major change when the Clinical Trial Regulation comes into application in 2019. The Regulation harmonises the assessment and supervision processes for clinical trials throughout the EU, via an EU portal and database. The European Medicines Agency (EMA) will set up and maintain the portal and database, in collaboration with the Member States and the European Commission.

The goal of Clinical Trial Regulation EU No. 536/2014 [↗](#) is to create an environment that is favourable to conducting clinical trials in the EU, with the highest standards of **safety** for participants and increased **transparency** of trial information. The Regulation will require:

- consistent rules for conducting clinical trials throughout the EU;
- information on the authorisation, conduct and results of each clinical trial carried out in the EU to be publicly available.

This will **increase the efficiency of all trials** in Europe with the greatest benefit for those conducted in multiple Member States. It aims to foster innovation and research, while helping **avoid unnecessary duplication** of clinical trials or repetition of unsuccessful trials.

When the Regulation becomes applicable, it will replace the existing EU Clinical Trial Directive (EC) No. 2001/20/EC [↗](#) and national legislation that was put in place to implement the Directive. It will also apply to trials authorised under the previous legislation if they are still ongoing three years after the Regulation has come into operation.

The authorisation and oversight of clinical trials remains the responsibility of Member States, with EMA managing the database and supervising content publication on the public website.

The background of the slide features a repeating pattern of stacked, light gray coins. Each coin has a stylized orange logo on its face, which consists of a circle with a dot in the center and a curved line above it, resembling a stylized 'i' or a specific symbol. The coins are arranged in several groups, some overlapping, creating a sense of depth and texture.

Obrigada!

(rmelero@iata.csic.es)