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# Extending the open monitoring of open science A new framework for the French Open Science Monitor (BSO)

Laetitia Bracco<sup>2</sup>, Anne L'Hôte<sup>1</sup>, Eric Jeangirard<sup>1</sup>, and Didier Torny<sup>3</sup>

<sup>1</sup>French Ministry of Higher Education, Research and Innovation, Paris, France

<sup>2</sup>University of Lorraine, France

<sup>3</sup>CNRS, France

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#### Abstract

We present a new Open Science Monitor framework at the country level for the case of France. We propose a fine-grained monitoring of the dynamics of the open access to publications, based on historical data from Unpaywall, and thus limited to Crossref-DOI documents. The economic models of journals publishing French publications are analyéed as well as the open access dynamics by discipline and open access route (publishers and repositories).

The French Open Science Monitor (BSO) website: https://frenchopensciencemonitor.esr.gouv.fr presents the results to date (last observation date December 2021). 62% of the 170,000 French 2020 publications are available in December 2021. This rate has increased by 10 points in one year. The level of open access varies significantly from one discipline to another. Some disciplines, such as the physical sciences and mathematics, have long been committed to opening up their publications, while others, such as chemistry, are rapidly catching up.

In the context of the COVID-19 pandemic crisis and the urgent need to open up scholarly outputs in the health field, a specific version of the French Open Science Monitor has been built: https://frenchopensciencemonitor.esr.gouv.fr/health. It monitors the open access dynamics of French publications in the biomedical field. It also analyses the transparency of the results of clinical trials and observational studies conducted in France. Only 57% of clinical trials completed in the last 10 years have shared their results publicly.

In contrast to other Open Science Monitoring initiatives, the source code and the data of the French Open Science Monitor are shared with an open licence. The source code used for the French Open Science Monitor is available on GitHub, and shared with an open licence. The code is split in modules, in particular for indicators computations https://github.com/dataesr/bso-publications and https://github.com/dataesr/bso-clinical-trials and the web user interface https://github.com/dataesr/bso-ui. The data resulting of this work is shared on the French Ministry of Higher Education, Research and Innovation open data portal: https://data.enseign ementsup-recherche.gouv.fr/explore/dataset/open-access-monitor-france/information/ and https://data.enseignementsup-recherche.gouv.fr/explore/dataset/barometre-sante-de-la-science-ouverte/information/.

The originality of the French Open Science Monitor also lies in the fact that it can easily be adapted to the level of an higher education and research institution. To date, some twenty higher education and research institutions have already used it to obtain reliable and open indicators on the progress of open science in their scientific production.

**Keywords**: clinical trials, journal business models, observational studies, open access, open science, scientometrics, unpaywall

## 1. Introduction

The French Open Science Monitor was launched in 2019 as part of the first French National Plan for Open Science (MESRI 2018). Its original methodology has between described in (Jeangirard 2019). It currently focuses on scholarly publications, for which at least one coauthor declares a French affiliation. It measures the rate of open access for these publications. It will eventually be extended to other dimensions of Open Science, whether they are transversal (management and opening of research data and softwares) or disciplinary.

To support the continuation of Open Science public policy with the second National Plan for Open Science (MESRI 2021), a new framework for the French Open Science Monitor has been produced. It introduces a monitor specific to the Health domain and also develops the features for the Open Access analysis.

The main goal of the current French Open Science Monitor is to produce a dynamic vision of the openness level evolution and to analyse in detail how publications are opened, developing specific indicators for open repositories on one hand and specific indicators for the dissemination platforms on the other hand.

The objective of the French Open Science Monitor in Health is to report on some aspects of Open Science specific to medical research and health, in relation to the sharing of scientific knowledge that has become a paramount urgency in the context of the COVID-19 pandemic (Waltman et al. 2021). The aim is to have indicators that will make it possible to take stock of the situation and monitor the public policies that will be implemented.

In addition to the open access to the publications, which is critical for all domains, the registration of clinical trials and observational studies, the publication of their results and the sharing of their data are specific dimensions in the Health domain, and more particularly in clinical research.

Clinical trials are research conducted on human subjects involving an intervention other than their usual care (delivery of a drug, treatment device, surgical procedure, etc.) for the purpose of developing biological, medical or public health knowledge.

Observational studies are "non-interventional" studies, also involving humans, but not an intervention other than the usual care of patients. They may focus on protocol compliance, adverse effects of a treatment after it has been put on the market, etc. This is the case, for example, with cohort studies, which consist on the statistical monitoring of a panel of individuals over the long term in order to identify the occurrence of health events of interest and inferring the related risk or protective factors.

This clinical research is subject to various biases, including publication biases, which are well identified by public health researchers. Amongst them, the most known is the tendency to publish only trials and studies which results are conclusive and in line with the expectations of the researchers who carried them out (these are known as "positive" results). The consequence of this bias is that the syntheses or meta-analyses carried out on the basis of medical publications with a view to guiding public health policies are in fact based on a partial and biased view of scientific knowledge.

Two main ways exist to correct this bias:

- systematic declaration of studies, before they are carried out, in dedicated registers;
- systematic publication of study results, even when they are "negative", for example through initiatives like Registered Reports.

Regulations have been implemented to improve transparency: in the United States, the declaration of clinical trials and their results is compulsory, and in Europe, the declaration of clinical drug trials will be compulsory as of 2022. In contrast, observational studies are not subject to any regulations regarding their reporting or publication.

The launching of the first Open Science Monitor by the European Union in 2017-2018 has been met with controversies, as the chosen project had included a big publisher as a subcontractor and, consequently, the underlying data used was not open but proprietary. That is almost a constant in the current Open Access and Open Science monitoring initiatives (see literature review in (Pölönen et al. 2020)). In contrast, the source code and the data of the French Open Science Monitor are shared with an open licence. The source code used for the French Open Science Monitor is available on GitHub, and shared with an open licence. The code is split in modules, in particular for indicators computations https://github.com/dataesr/bso-publications and https://github.com/dataesr/bso-clinical-trials and the web user interface https://github.com/dataesr/bso-ui. The data resulting of this work is shared on the French Ministry of Higher Education, Research and Innovation open data portal https://data.enseignementsup-recherche.gouv.fr/explore/dataset/open-access-monitor-france/information/ and https://data.enseignementsup-recherche.gouv.fr/explore/dataset/barometre-sante-de-la-science-ouverte/information/.

## 2. Method

## 2.1 Publications

#### 2.1.1 Perimeter definition

- 2.1.1.1 French Open Science Monitor The French Open Science Monitor is a tool that aims at steering the Open Science policy in France. As such, it produces statistics that are analyzed over time, and it has to focus on "French" productions. As stated in (COSO 2018) and recalled in the introduction, we want to use only public or open datasources, contrary to other monitoring systems like the German open access monitor https://open-access-monitor.de/open-access which relies on partially on proprietary databases. As the monitor perimeter is not defined by these selective databases, there are only two limits to the imposed to the scope of the monitor:
  - only publications with at least one author who has a French affiliation are considered. Conversely, the nationality of the authors does not play a role in the selection. This choice raises the issue of access to affiliation information: affiliation metadata are present in specific sources, like PubMed, but quite rarely appear in the whole Crossref data. Such information is the more critical as France, contrary to some Norther European countries, has not yet built a comprehensive CRIS system. To fill in the gaps, we proposed to crawl the affiliation information displayed publicly from the publications webpages. On top of that, identifying a country from an affiliation text is far from being straightforward. To take an actual example, think about an affiliation stating "Hôtel Dieu de France, Beirut, Lebanon": this does not refer to a French affiliation even though the word "France" is present in the address or institution field. We use an automatic detection algorithm, based on Elasticsearch, described in (L'Hôte and Jeangirard 2021), to infer the relevant countries from the authors affiliation field.
  - only publications associated with a Crossref DOI are considered. We wish to avoid duplicates, as counting twice (or more) a publication would add a bias to the statistics being produced. It is then crucial to use a Persistent Identifier: as we chose to use Unpaywall data for Open Access (OA) discovery, it only include Crossref DOI documents, which led us to adopt the same perimeter. We are aware that this is currently a bias, though less important than commercial databases against some disciplines, most notably Humanities and Social Sciences, and some type of research output. Unpaywall delivers open data and enables to snapshot the whole database, which is an asset to analyse OA dynamics.

All publications types are considered (journal articles, proceedings, books, book chapters, ...) as soon as documents are associated to a Crossref DOI. Many types are being coded in the metadata, but for the sake of results and figure clarity, we regrouped them in the following categories, namely journal

articles, proceedings, preprints, book chapters, books, the rest being gathered in an 'Others' category. It is important to note that the 'preprint' type does not appear as such in the available metadata (it is generally declared as a journal article). Some preprint detection is based on the dissemination platform information. At the time this article is written, only the Cold Spring Harbor Laboratory platforms (BioRxiv, MedRxiv) are covered, but it will be extended as soon as other preprint dissemination platforms would start using Crossref DOIs, or whether Unpaywall reverts its policy and covers Datacite DOIs, which would enable us to include ArXiv preprints.

2.1.1.2 French Open Science Monitor in Health The current French Open Science Monitor also introduces a focus on the Health domain. Delimiting a clear perimeter for Health is not very easy. For now, we have simply chosen to consider in that scope all PubMed publications, and only these. The publications' data used in the French Open Science Monitor in Health is then a subset of the publications described above, adding the PubMed presence criterion to the other criteria (author affiliation, Crossref DOI). Note that "Health" is seen more as a domain than as a discipline. In fact, publications from a lot of disciplines are taken into account in the French Open Science Monitor in Health. A domain-specific set of disciplines is used in the French Open Science Monitor in Health, as described below.

#### 2.1.2 Open access dynamic

From the first edition of the French Open Science Monitor, it was clear that the open access rate was far from stable though time, so we should try to capture the opening dynamics (Jeangirard 2019). Indeed, the immediate open access has focused most attention, but we know it does not represent the totality of the open access, notably considering the various publishers mobile barriers, but also theirs and funders and national embargo policies (Laakso and Björk 2013). Therefore, for a given set of publications, say the publications published during the year Y, it is important to measure the open access rate at different points in time, for example at year Y+1, Y+2...

To do so, it becomes necessary to historicize the database containing the open access information. So, instead of maintaining a database that keeps track of the opening of each publication, which is the current Unpaywall data policy, we have to make regular snapshots of the whole Unpaywall database. Each snapshot is used as an observation date to measure the open access rate. It is important to note that this method natively embeds the potential open access discovery errors from the underlying Unpaywall database. That includes false negative (a publication is actually opened at that time but it is not detected as such) and false positive (wrongly seen as opened whereas it is closed). As a side note, it would also enable us to follow "temporary open" publications, resulting from new publishers policies adopted for Covid-19 related publications (Arrizabalaga et al. 2020).

This method of analysis therefore reveals two temporal dimensions: publication dates and observation dates. Obviously, the observation date must be after the publication date. To avoid that the proliferation of possible analyzes blurs the analysis, we propose to look at two elements:

- A key ratio that is the **1Y Open Access rate**: it represents the open access rate of the publications published during year Y and measured (observed from the snapshot of the OA discovery database) at one point in time during year Y+1 (generally in December if the data is available).
- Also, the **shape of open access curve** (open access rate function of the publication year). For a given observation date, the open access rate can be estimated broken down by publication year. This is translated into a curve of the open access rate as a function of the publication year (at a given point in time which is the observation date). This curve may have any shape, and in particular it is not always expected to be a monotonic increasing one. Indeed, a monotonic increasing curve means that more recent publications are more and more open: that may (hopefully!) happen, but moving barriers and embargoes would actually produce another type

of shape, that would be an inverted-V shape. The figure 1 illustrates different shapes of Open Access curves.

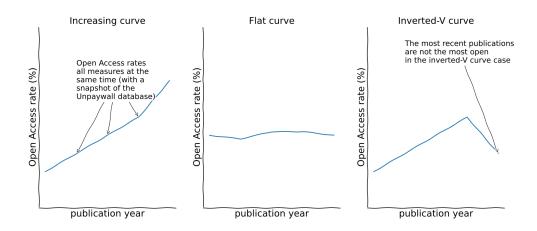


Figure 1: Different shapes of Open Access curves

From an observation date to another, the OA curve shape may change. This evolution of the shape gives an insight on the opening speed evolution. Indeed, moving from an inverted-V shape, where the most recent papers are not the most open, to an increasing shape would be a strong evidence of the opening acceleration. The figure 2 illustrates the evolution from an inverted-V shape, to flat and then to an increasing OA curve shape.

#### 2.1.3 Open access types

As Unpaywall is the Open Access discovery tool we used, we initially based our results on the OA classifications described in (Piwowar et al. 2018). It breaks down the OA types in 5 categories: 'Gold', 'Hybrid', 'Bronze', 'Green', 'Closed'. These categories are also present in the Unpaywall database (and oaDOI API) in the field 'oa\_status'. We first simply regrouped the categories 'Gold', 'Hybrid' and 'Bronze' under a 'Publisher hosted' label. However, we now propose another classification that we think more appropriate, at least for the French OA policy steering.

(Piwowar et al. 2018) defined 'Green' as 'Toll-access on the publisher page, but there is a free copy in an OA repository'. That implies that a publication that would be free to read on the publisher webpage and that would, at the same time, have a free copy on a repository would not be counted as 'Green'. That derives from the idea that the Version of Record (VoR), available on the publisher website, is the preferred OA version of the publication (REF à ajouter). As a consequence, the repositories contribution to OA is mechanically reduced in favor of the publishers one. This therefore blurs the picture of the extension of repositories impact. That led us to propose a first level of analysis, with 3 categories (excluding 'Closed'):

- hosted only on an open repository: Toll-access on the publisher page, but there is a free copy in an OA repository, corresponging exactly to the 'Green' definition of (Piwowar et al. 2018), that we could rather label 'Green only'
- hosted only by the publisher: Free to read on the publisher webpage, but no free copy in any OA repository harvested by Unpaywall.
- hosted on an open repository and by the publisher: Free to read on the publisher webpage and there is a free copy in an OA repository.

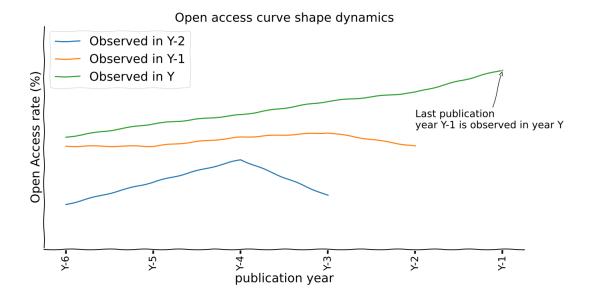


Figure 2: Open Access curve dynamics

Obviously, this does not impact the overall Open Access rate, but this balanced division, with no preference for the VoR, gives a different picture. It seems that a similar choice has been recently made to represent COKI data and its sources of openness https://openknowledge.community/dashboards/cokiopen-access-dashboard/

The figure 3 shows the kind of impact choosing one or the other OA type break down.

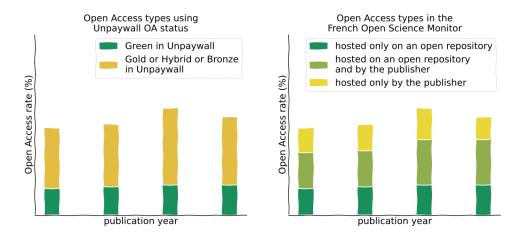


Figure 3: Open Access hosting types

Another graphical way to represent this distribution is to use a bubble chart (figure 4). Each bubble represents a cluster of publications (one bubble is the equivalent for each discipline, for each dissemination platform ...), its size depends on the number of publications in the cluster. The x-axis represents the share of OA publications hosted by the publisher, corresponding to the sum of publisher-only and publisher / open repository hosted publications. Conversely, the y-axis represents the share of OA publications hosted on a repository, corresponding to the sum of open repository-only and open repository / publisher hosted publications.

The source of data used to compute these OA types is still Unpaywall, but instead of the 'oa\_status' field, we then use the 'oa\_locations' field. For a publication which is in open access, it lists all the existing available copies that Unpaywall detected, at the time of the snapshot. Each location is described, in particular with an URL that gives a link to the given copy, and some metadata for the location is associated, in particular the 'host\_type', that take two possibles values, 'publisher' or 'repository'. It is important to note that, for now, preprint servers are always considered as repositories.

#### 2.1.4 Discipline and language impact

All disciplines and publication languages are covered, while no metadata exists to describe the discipline or the publication language. To enrich the metadata, we then rely on machine learning approaches, that infer discipline and language from the available metadata.

For the language detection, only the title and abstract are used if available, with the lid.176.bin Fasttext word embedding machine learning algorithm (Joulin et al. 2016).

Discipline detection also uses journal and keywords metadata if available. A general classifier is implemented for all domains, which classifies the publications into 10 macro disciplines: Mathematics, Chemistry, Physics & astronomy, Fondamental biology, Medical research, Computer sciences, Earth science ecology energy & applied biology, Humanities, Social sciences, Engineering. It is trained on data from the Pascal & Francis database and uses a Fasttext classifier. More details are discussed in the previous paper (Jeangirard 2019).

A domain-specific classifier is implemented for the Health domain. It classifies the publications into 17 disciplines, built from the Fields of Research taxonomy. The full methodology is detailed in (Jeangirard 2021).

The main purpose of these metadata enhancements is to be able to analyse the open access rate

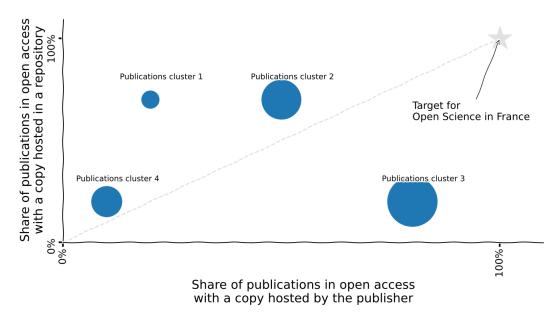


Figure 4: Share of publications in open access hosted on an open repository vs. by the publisher

according to languages and disciplines. We expect to observe differences not only in the global OA rate (Which discipline is the most open?), but also in the dynamics trends (Which discipline shows the strongest increase over time?) or in the opening practices (relying on publisher hosted open access versus open repositories).

#### 2.1.5 Publishers and dissemination platforms strategies

**2.1.5.1** Identification of the dissemination platforms The data in the 'publisher' field of Crossref shows many inconsistencies. There are many journals, with a single ISSN, that belong to more than one publisher - whether they are different lexical forms or refer to actual different entities. Consequently, we performed a triple grouping in order to facilitate the coding of an economic entity disseminating the journal in question.

- Firstly, we have considered the diversity of lexical forms of the same publisher, existing in developed form and in the form of acronyms, including or not its economic status (LLC, Ltd.,...);
- Secondly, we have taken into account the capitalist evolution of the sector, which is marked by a growing concentration, with successive takeovers (Larivière, Haustein, and Mongeon 2015). The latter do not necessarily make the old group names vanish, as they are often used as a brand name of the new entity(e.g. Palgrave being a brand of the Springer Nature group);
- Thirdly, we have taken into account the possible distinction between publisher and dissemination platform, with many scholarly societies remaining the owner and publisher, but delegating the dissemination of their publications to a given publisher/disseminator though multi-year contracts.

We historicized the last two groupings to account for the effective date of the link between these different entities. All coding is available in the open source code hosted at https://github.com/dataesr/bso-publications/tree/main/bso/server/main/publisher.

- **2.1.5.2** Business models and open licenses As explained above, the 'oa\_status' in Unpaywall data belittles the role of open repositories. It also invisibilize Diamond open access, indifferently mixing in the same 'Gold' category all publications in an open-access journal that is indexed by the DOAJ, whether Article Process Charges (APC) are part of the business model or not. That is why we introduce another level analysis, about the dissemination platform business model, with 3 categories:
  - **Diamond**: articles published in an open-access journal indexed by the DOAJ, and without APC (according to the DOAJ data). This category may be under-estimated as many journals have a no-APC model are not currently included in the DOAJ (Bosman et al. (2021))
  - (Full APC) Gold: articles published in an open-access journal (using the field 'journal\_is\_oa' = True from Unpaywall) and with an estimated APC, as described above.
  - **Hybrid**: publications published in a journal that is not full open access (using the field 'journal\_is\_oa' = False from Unpaywall) and with an estimated APC, as described above.
  - Other: all other cases, in particular publications with moving barriers, but also cases for which no information about APC has been collected. This category may be over-estimated as some journal have no APC but this information is not present in a structured database.

The objective of this level of analysis is to separate different business models (APC vs Diamond vs Hybrid), not to analyze the open licenses associated to the OA copies, so this categorization is quite different from the Gold / Hybrid / Bronze from (Piwowar et al. 2018).

For that matter, a third analysis level is used that distinguishes, for open access publications:

- Creative commons licenses (cc0, cc-by, cc-by-nc etc ...)
- Other licenses (publisher specific, country-specific ...)
- No license

To be clear, the no license category does not mean that the publications are closed, on the contrary they are in freely available but no open license was detected, meaning the reuse conditions, beyond reading, are not defined. They are certainly not BOAI-compliant (REF), but considered as "open" in our context.

Again, the informations from the field 'oa\_locations' comes from Unpaywall, therefore the results depend on the quality of the Unpaywall database.

- **2.1.5.3** Article Processing Charges (APC) estimation Estimating APC for each journal article remains difficult as few open sources exist. We leverage on the openAPC database (at the publication level) and on the DOAJ data (at the ISSN level). We use the following heuristics to estimate the APC of a publication:
  - If the DOI is not in open access with a free copy on the publisher webpage, there is no APC
    estimation to make.
  - Else, if the DOAJ specifies there are no APC for the ISSN, then it is a Diamond DOAJ OA, with no APC
  - Else, if the DOI is explicitly in the openAPC database, we simply use the APC from openAPC.
  - Else, if the DOI is not in the openAPC database, but its ISSN or publisher is, with a sufficient number of observations, we use the mean of the APC observed for the same ISSN or the same publisher, during the same year if enough data is available, or over the whole openAPC database otherwise.
  - Else, if the DOAJ specifies there are APC for the ISSN, we simply use the APC from DOAJ, after a conversion to Euros if needed (based on the exchange rate at the publication date).

• Otherwise, no estimation is made.

We are aware that this estimation is far from being perfect, but it still brings some insights. On top of that, even if we focus on French publications (publications with at least one author with a French affiliation), the sum of the APC estimated is higher than the actual amount of APC money spent by French institutions, as a large share of the publications are co-authored with scholars affiliated to foreign institutions. Informations on the corresponding author could be a proxy to focus on APC spent by France but for now, we do not have an open, reliable and massive source for this information.

#### 2.1.6 The role of the open repositories

#### 2.1.7 Other analysis axes

In the case of the Health domain, we use metadata coming from PubMed. These metadata are quite rich and enable extra analysis. In particular, some **funding metadata** are present in PubMed, as well as the **affiliations for each author** (it is far from being the case when using other sources and scrapped metadata).

PubMed gives information on grant declaration. To be clear, the absence of this metadata does not mean that there was no specific funding leading to the given publication. So the only thing we are able to do is to check whether a correlation exist between the open access rate and the presence of the grant metadata in PubMed.

As the affiliations information is given for each author, we can use (L'Hôte and Jeangirard 2021) to infer the country of affiliations of each author. We wish to analyze whether the country of affiliation of the corresponding author correlates to the open access rate or not. Unfortunately, the corresponding author metadata is not available, that is why we chose an approximation looking at the affiliation country of the **first and the last authors**. That will give an insight to know whether, for French publications, the OA rate is in general higher when one of the first or last authors has a French affiliation, or, conversely, if the OA rate is higher when the first and last author are affiliated abroad.

### 2.2 Clinical trials and observational studies

The French Open Science Monitor focused only on publications. Current work is being conducted on monitoring Research Data and Software Code. The French Open Science Monitor in Health, however, already introduces new research objects specific to the Health domains: clinical trials and observational studies.

In the USA, reporting and publication of results is mandatory for all clinical trials. The reporting registry used is https://clinicaltrials.gov/. This website is also used by many international actors. It also welcomes reports of observational studies, though this reporting is not mandatory.

In European Union countries, the reporting obligation will only extend to clinical drugs from 2022 on. The European registry https://www.clinicaltrialsregister.eu/ (EUCTR) therefore mainly includes clinical trials involving medicines, and less frequently observational studies, clinical trials involving surgical protocols, medical devices or psychotherapeutic protocols.

The issue of opening up or sharing data arises for clinical research in the same way as for other areas of scientific research. However, it has a particularly complex dimension, since it involves personal data, some of which directly concern the health of individuals. Nevertheless, it is possible to define the modalities for sharing this data.

Two dimensions will be developed:

- The openness of the results and publications when the study is completed.
- The declaration of clinical and observational studies in these public registries.

#### 2.2.1 Perimeter

For now, two datasources are used to collect metadata about clinical trials and observational studies: clinicaltrials.org and EUCTR. The former one provides an API while the latter one does not; that is why the information is crawled from the website. Only the trials and studies that involves at least **one location in France** are analyzed.

Some trials or studies appear in both registries, the matching between the two databases being done based on the PIDs NCTId (from clinicaltrials.org) and eudraCT (from EUCTR), both registries keeping track of external PIDs. However, duplicates may still remain when no link has been established between the existing PIDs in both registries.

To distinguish clinical trials on one side and observational studies on the other, we use the study type field, that can be either 'Interventional' (for clinical studies) or 'Observational' (for observational studies).

#### 2.2.1 Main opening indicators

Two key types of indicators are analyzed:

• The declaration of results and / or scholarly publications after a trial or study is completed. (Goldacre et al. 2018) showed that a large fraction of trials do not report their results in the databases or publications. On top of the results declaration rate itself, we look into the results' date of registration, assessing the delay between the end of the trial and the actual reported results date.

We propose both indicators, mixing or separating results and scholarly publications. For publications, it is important to note that only the metadata from the studies registries are used, without trying to link trials to DOIs using the publications metadata (with PubMed for example). The open access status of these publications is also retrieved from the Unpaywall data.

• The delay to register the study: is the trial or study publicly registered before it actually starts, or is it done afterwards? And how many months is the actual delay to register? Does it evolves over time?

#### 2.2.2 Lead sponsor impact

(Goldacre et al. 2018) gives evidence that the rate of results declaration is very impacted by the type of lead sponsor, commercial sponsors having a much higher declaration rate. We therefore propose to break down most of the analysis axis with the type of lead sponsor, being either academic or industrial. This categorization has been done manually based on the lead sponsor name.

## 2.3 'Local' Open Science Monitors

The University of Lorraine was the first institution to provide a local version of the French Monitor (Bracco 2022): https://scienceouverte.univ-lorraine.fr/barometre-lorrain-de-la-science-ouverte.

This local version, published during spring 2020, was designed with reusability in mind. For this purpose, the code has been detailed step by step in Jupyter Notebooks and includes a readme file explaining all the required actions to obtain its own Monitor.

The code created on this occasion is freely accessible (Bracco 2020).

The availability of the code was combined with numerous training sessions as well as individual assistance provided by the University of Lorraine to each institution that requested it.

Following the publication of this code, many institutions were able to generate their own Open Science indicators. This enthusiasm for local implementation has underlined the need for institutions to have reliable and effective tools for monitoring Open Science.

The new version of the national Monitor enables, directly from the website, to generate graphs from a list of DOIs previously sent to the French Ministry of Higher Education, Research and Innovation team. The University of Lorraine has been asked to test and implement this new version.

The constitution of the DOI corpus remains an essential step for institutions. The code proposed by the University of Lorraine makes it possible to generate this list simply by crossing various databases.

This simplified version will probably encourage other institutions to establish their own Monitor.

## 2.4 Data collection system and architecture

In this section, we will try to present the global workflow to collect, enrich and consolidate the data as described before with the technical and the storage challenges.

We collect data from multiple sources (PubMed, Crossref, parsed html...), and then try to determine the affiliations' countries. From the Crossref DOIs, we collect more details about that publication via Unpaywall (title, published year, ISSNs, but also open access locations if any).

Each step consumes time and CPU. Assuming any step can fail at any time, we choose to develop each step as independent and idempotent.

From the different datasources, we store the raw data on Object Storage on the public OVH Cloud. These data are then transformed into a common 'pivot' json schema, and enriched with affiliations countries, so that only the French publications are kept in the rest of the process. These publications metadata are then enriched with Unpaywall informations (open access locations), openAPC and DOAJ informations to infer if APC were paid or not.

Eventually, the data is loaded in an elastic search cluster that is consumed by the French Open Science Monitor User Interface.

A similar workflow, yet simpler is set up for clinical trials.

### 3. Results

The results are extracted from the French Open Science Monitor website https://frenchopensciencemonitor.esr.gouv.fr from February 2022.

## 3.1 Open access dynamics in France

#### 3.1.1 General dynamics

The steady increase in the open access rate observed each year since 2018 is an indicator of the impact of public policies in favour of open access. It is a proof of the evolution of researchers' publication practices, the strengthening of open access publication infrastructures and the strategies of scientific publishing actors. Open access to publications is an evolutionary process over time. A publication that is not available in open access at the time of its publication may become so in the following months and years, through various mechanisms: deposit by the author in an open archive after a period of embargo imposed by the publisher or the application by the publisher of a moving wall, i.e., a time limit at the end of which it itself makes the publication available in open access.

The figure 7 presents, for each observation date since 2018, the open access rate of French scientific publications published during the previous year. The observations made during the current year are

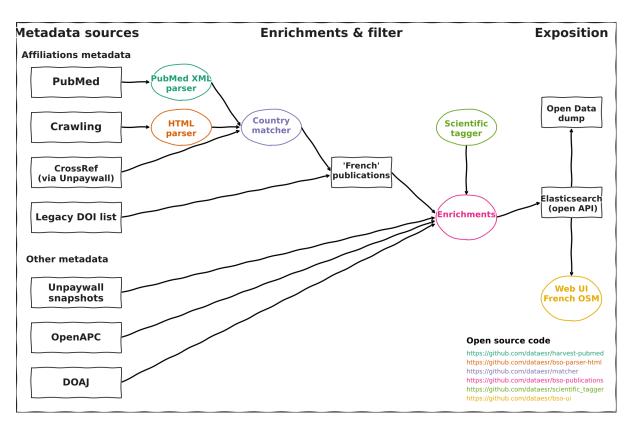


Figure 5: Global overview of the publications data flows

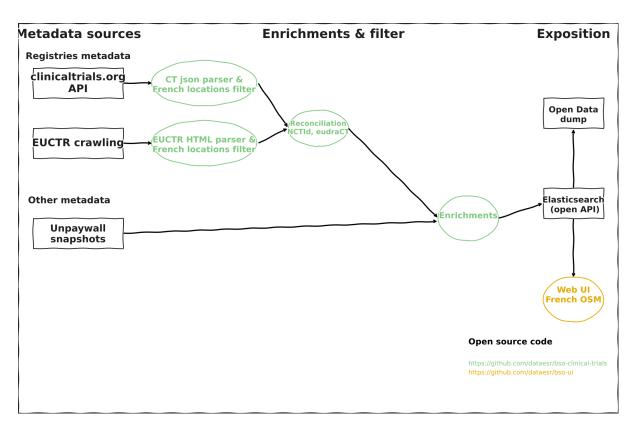


Figure 6: Global overview of the trials and studies data flows

updated every quarter. Thus, 52% of french scientific publications published in 2019 were in open access in 2020 (observation date). And 62% of french scientific publications published in 2020 were open in 2021. The access rate has thus increased by 10 points in just one year.

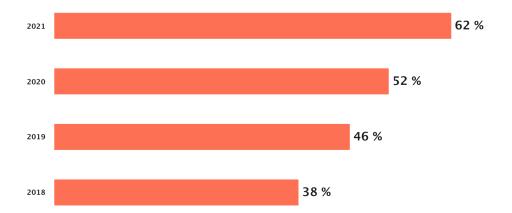


Figure 7: Open access rate of scientific publications in France published during the previous year by observation date

The figure 8 presents, for each observation date, the open access rate of scientific publications in France by publication date. Each line represents the open access rates observed for an observation date, and the open access rates are expressed as a function of the publication year. For each year of publication, it is observed that the open access rate increases according to the date of observation. This is due to the process of releasing the most recent publications through the expiry of moving walls or deposits on open archives after an embargo period. As a result, the open access rate of publications released in 2017 has increased from 38% in 2018 to 51% in 2021. When the open access rate is higher in the latest year of publication than in previous years, this is an indication of a shortening of the timeframe for open access provision.

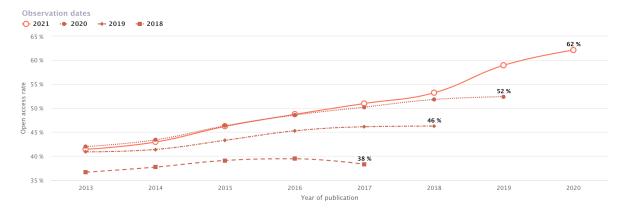


Figure 8: Evolution of the open access rate of scientific publications in France by year of observation

Open access to scientific publications can be achieved through several routes: natively open access publication by the publisher on a dissemination platform or deposit by the author in an open repository. These two routes are not exclusive, as a publication may be available both on an open repository and on the publisher's publishing platform. This simultaneity, which tends to increase over time, is a factor

of resilience since it makes it possible to offer editorial quality and guarantee the durability of access to French scientific publications. We observe that, for publications published in 2020, 28% are open via both routes, 18% only via an open repository and 16% only via the publisher (figure 9).



Figure 9: Distribution of scientific publications in France published in 2020 by opening route (observed in 2021)

The figure 10 shows, for the most recent observation date (2021), how open access publications in France issued in the previous year are distributed by opening route.

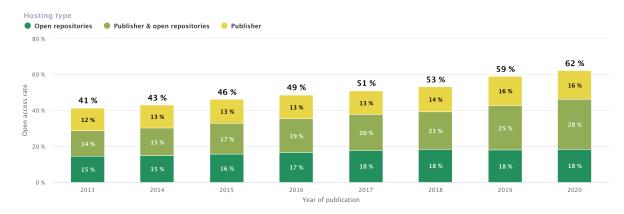


Figure 10: Distribution of the open access rate of publications in France per publication year and by OA route (observed in 2021)

Scientific publications take a variety of forms: articles are the most common, but there are also books (monographs written by a single author or collective works bringing together various contributions), conference proceedings, preprints, i.e. articles proposed for discussion before submission to a scientific journal, etc. The preferred types of publication differs according to disciplines and disciplinary communities. Each type of publication has its own dissemination logic, which explains why open access rates vary from one to another. In particular, we note that the monitor measures a ratio of 65% open access for journal articles, and 30% open access for book chapters (figure 11). Open access initiatives have historically started with journals and articles. Books and chapters are less involved in the open access process, at least for their Crossref DOI part.

The monitor makes it possible to measure both the domination of English as a scientific language and the significant maintenance of production in French, which contributes to the multilingualism of

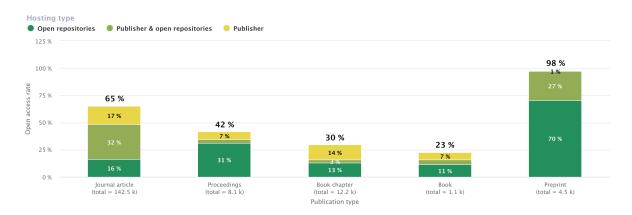


Figure 11: Open access rate by type of publications in France (publications from 2020)

scholarly communication. Several factors must be taken into account in order to interpret the difference in the rate of open access according to the languages in which French researchers publish: international standards in terms of open access, the specific practices of disciplines that publish mainly in French or English, and the development of open access publishing capacities in the various linguistic areas.

In particular, we note in figure 12 that among publications published in 2020, there are 144.4 k publications in English of which 95.3 k are open and 49.1 k are closed (i.e. an open access rate of 66%), and 21.2 k publications in French of which 7.8 k are open and 13.5 k closed (i.e. a rate of 37%). French-language publications are therefore less open than English-language publications. Publications in Spanish, German and Portuguese represent smaller numbers, statistically less significant.

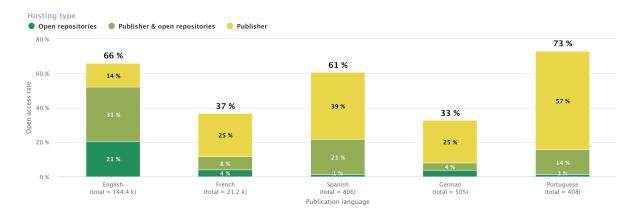


Figure 12: Open access rate by language of publications in France (publications from 2020)

## 3.1.2 Open access dynamics in the different scientific fields

The level of openness of publications varies significantly from one discipline to another, depending on the involvment of scientific communities and the diversity of their practices. These variations can also be observed in the trajectory of the level of openness over time. Some disciplines, such as astronomy and mathematics, have a long-standing tradition of opening up publications, while others (chemistry, fundamental biology) have experienced more recent acceleration. All of them, nvertheless, are part of a dynamic of openness. There may be artefacts linked to data sources (in SSH and computer science, some of the publications are not identifiable by our methodology).

For each year of observation since 2018, the monitor estimates the open access rate of scientific publications in France published during the previous year. The figure 13 presents, for each disciplinary field, the evolution of the open access rate observed each year for the previous year's publications. This visualization makes it possible to observe and compare the opening dynamics of the different disciplines: each point on a line represents the rate observed during an observation year. Thus, the greater the distance between two consecutive points, the more the open access rate has evolved between two years of observation. We observe, for example, that during the last years of observation, it is the chemistry that marked the largest increase in the rate of open access publications compared to 2018, going from 28% to 64% open.

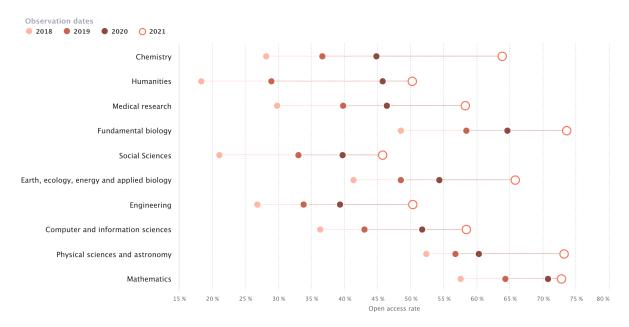


Figure 13: Dynamics of the evolution of the rate of open access publications in France for each discipline

Not all disciplines adopt the same vectors for publishing in open access. For some, the practice of depositing in an open archive is historically rooted and legitimate. Mathematicians, physicists and computer scientists have long practiced open archives upstream of journal submission. The humanities and social sciences more readily entrust their openness to publishers. Between the two, there are many situations, depending on the organization and history of the disciplines. The most striking fact in the field of biology-health is the existence of an international policy, initially at the initiative of organizations funding research projects, which leads to a systematic deposit, with or without embargo, in PubMed Central (PMC) in the United States, or Europe PMC in Europe, which means that these disciplines open up both on the publishers' platforms but also in a globally used open archive. From the point of view of the National Plan for Open Science, the cohabitation of the two models (openness via publishers and via open archives) presents neither contradiction nor disadvantage. On the other hand, it allows a good resilience of the system.

For each discipline, the figure 14 represents, for publications in France released in 2020 and at the most recent observation date (2021), what is the respective share of the different routes to open access: publication in open access by the publisher, deposit in one or more open archives, or both routes simultaneously. Note that from one update to the next, each individual publication may change status, for example from "open via publisher" to "open via publisher and open archive" if the publication has been deposited in an open archive in the meantime. In particular, we note that for publications published in 2020 in medical research, 9% of publications are open via the open archive route, 31% are open via the publisher & open archive route and 17% are open via the publisher route.

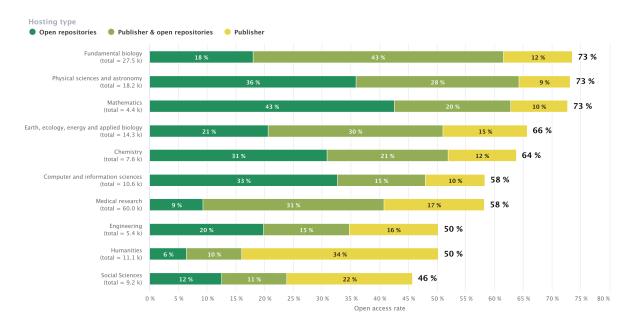


Figure 14: Distribution of publications in France by opening route for each discipline (publications of 2020)

In figure 15, each discipline is represented by a bubble whose size is proportional to the volume of publications in France released in 2020. The positioning of the bubble indicates which are the preferred channels for opening publications in the discipline concerned: the further to the right the bubble is positioned, the higher the share of publications opened by the publisher for that discipline; the higher the bubble is positioned, the higher the share of publications deposited on an open archive. When the bubble is positioned at the top right of the graph, it means that publications from this discipline are open simultaneously on the publisher's publishing platform and on one or more open archives. Thus, mathematics is very keen on open archives and the humanities are more willing to entrust their openness to publishers. If the sum of the share of publications opened by the publisher and the share on open archive is greater than 100%, it means that some publications are deposited in 2 (or more) places at the same time.

#### 3.1.3 Open access dynamics and publishers policies

The global publishing landscape is extremely diverse. There are about 12,000 scientific publishers around the world, each with a different history. They may be commercial or not-for-profit, national or multinational publishing companies, scholarly societies, university presses with public status, etc. Some actors have chosen to publish in open access from the start, while others have more or less strongly and recently engaged in a transition towards open access, with various models. There is a shared tendency to publish more and more in open access. We are not measuring here the open access rate of French publishers, but of the publishers in which French researchers publish. Nor do we measure the gradual reduction in the duration of mobile barriers.

For each year of observation since 2018, the graph represents the share of scientific publications in France published during the previous year that are made available in open access by their publisher. Some of these publications may be simultaneously available in an open archive. On the other hand, publications that are only available via an open archive are not taken into account. Thus, in 2021, 44% of scientific publications in France released in 2020 were made available in open access by their publisher (figure 16).

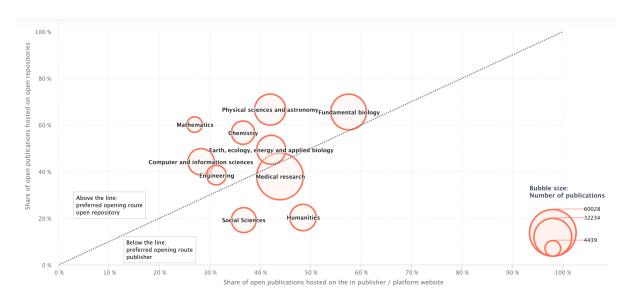


Figure 15: Positioning of disciplines according to the preferred route for opening their publications in France (publications of 2020)

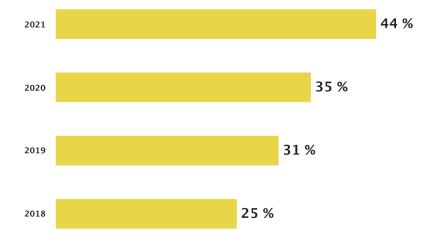


Figure 16: Share of scientific publications in France made available in open access by their publisher, by year of observation, for publications published during the previous year

In figure 17, for each observation year and by publication date, the share of scientific publications in France that are made available in open access by their publisher is displayed. Each line represents the rates observed at an observation date, and the rates are expressed as a function of the volume of publications published in the year observed. It can be seen that, for publications released in a given year, the rate of open access by the publisher varies from one observation date to another. This is due, for example, to the process of releasing the most recent publications through the expiry of moving barriers. Thus, between 2018 and 2021, the share of publications released in 2017 that are made available in open access by their publisher has increased from 25% to 33%.

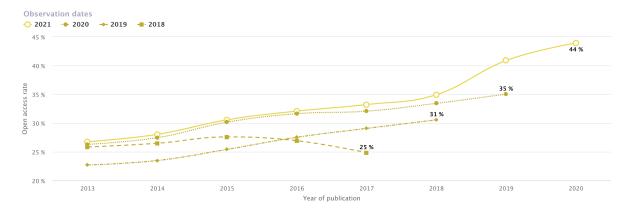


Figure 17: Evolution of the share of publications in France made available in open access by publisher by year of observation

The dissemination of open access articles by academic journal publishers is based on various business models. Some publishers have replaced traditional subscription revenues with the payment of publication fees (APC) charged on a per-article basis to researchers, their institutions or their funders. This change of model is often done at the level of an entire journal (full APC model), but other publishers maintain the subscription while offering authors the choice to open their article in return for the payment of a publication fee (a model known as hybrid), thus establishing a particularly unreadable double payment. Some publishers do not charge publication fees but mobilize, in the context of a non-commercial activity, funding from states, public actors, universities or other non-profit organisations, in order to finance the editorial and publication activity upstream: this is the so-called diamond OA model (Bosman et al. (2021)). Finally, other models exist, such as the one where the publisher collects subscriptions for the most recent publications while releasing them in open access after a set period of time (moving barrier).

The figure 18 shows the distribution of scientific articles published in 2020 and distributed in open access by their publisher, according to the business model of the journal in which they are published. It distinguishes between four types of economic models: articles published in full open access journals that do not charge publication fees ("diamond"), articles published in full open access journals that do charge publication fees ("Gold full APC"), and articles published in hybrid journals (where only some part of the content is in open access and the other part is available through individually paid publication fees), and all other cases. The "Diamant" part is probably underestimated. In particular, we observe that for scientific publications in France released in 2020, diamond represents 9% of the articles disseminated in open access by their publisher.

In 2016, the French law for a Digital Republic made it possible for researchers who have published a scientific article with a publisher to deposit the accepted version of the article for publication in a open repository, subject to a time limit (embargo) that can be set by the publisher but cannot exceed 6 months for science, technology and medicine and 12 months for the humanities and social sciences. Deposit in an open archive is therefore a way to counterbalance the restrictive open access policy of some publishers and it plays a decisive role in providing access for all to French research results.

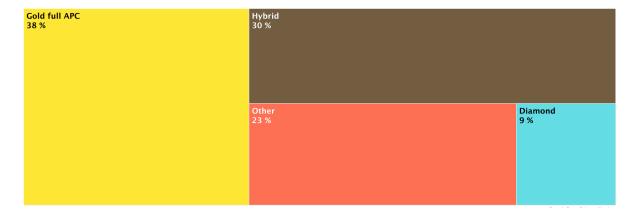


Figure 18: Distribution of business models for articles published in 2020 and distributed in open access by their publisher

Conversely, when the publisher publishes natively in open access, deposit in an open archive may appear less necessary to authors. However, it remains useful and desirable. Indeed, a deposit on the national open archive HAL guarantees the perennial conservation of the content and the control of the results of French scientific research, regardless of the hazards that affect publishers or their distribution platforms.

Open access to scientific publications implies not only the possibility to read them without having to overcome price or technical barriers, but also the possibility to reuse them by citing their author(s). The precise conditions of reuse are defined by means of licences, in particular the Creative Commons licences that are most commonly used. Thus publishers implementing an open science policy should not only release publications in open access, but also attach a free license securing the reuse of the content by readers, whether they are researchers, teachers, professionals or other social actors. The use of licences thus facilitates the dissemination of scientific knowledge above and beyond academic communities.

The figure 21 indicates, for scientific publications in France released in 2020 and distributed in open access by their publisher, what proportion is accompanied by an open licence specifying the conditions of re-use. The 'See details' button allows a more detailed view of the type of licence used, in particular for Creative Commons licences. It is possible to select a publisher or a publication platform (when several publishers use the same platform, the platform level has been preferred). Thus, 65% of scientific publications in France released in 2020 that are distributed in open access by their publisher are accompanied by an open licence. Within the open licences, the CC-BY licence is the most popular with 45% of the publications.

The figure 22 indicates, for each academic publisher or publishing platform in open access in 2020, the proportion of them that are accompanied by an open licence. The 25 publishers or platforms publishing the most French scientific articles in open access are taken into consideration, in decreasing order. When several publishers use the same publication platform, the platform level was taken into consideration. Please note that without a license, the normal copyright applies. Thus, Elsevier put an open licence for 28% of its French open access publications published in 2020.

One model for financing open access to scientific publications is based on the payment of publication fees (APC) which publishers charge per article and which are paid by researchers, their institutions or their funders. This model is mostly used by commercial publishers, would they be native OA or have transitioned from subscription models. It is very expensive and uncertain for public research institutions, especially as it is accompanied by an inflation in the number of articles published. It

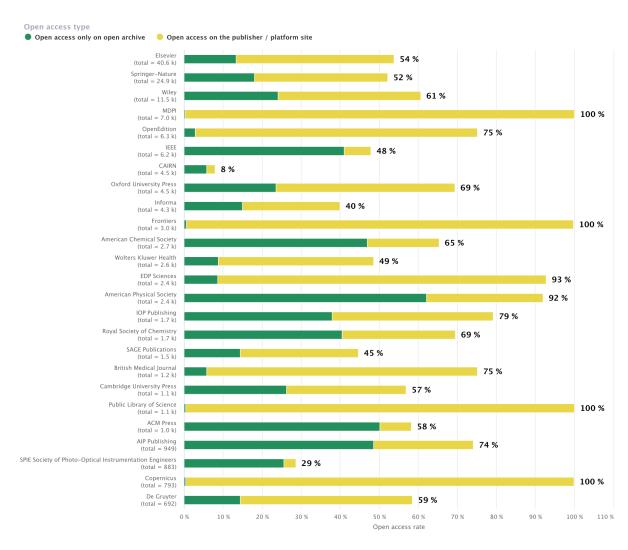


Figure 19: Opening routes for scientific publications in France released in 2020 by the most important publishers or publishing platforms in terms of volume (top 25)

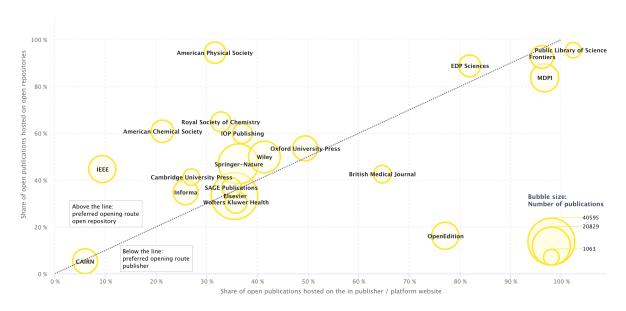


Figure 20: Positioning of publishers and publishing platforms according to the preferred route for opening up the French publications they distribute

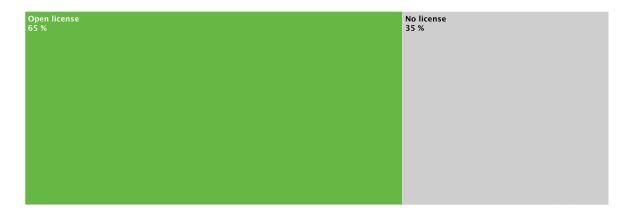


Figure 21: Distribution of open scientific publications in France by type of license used

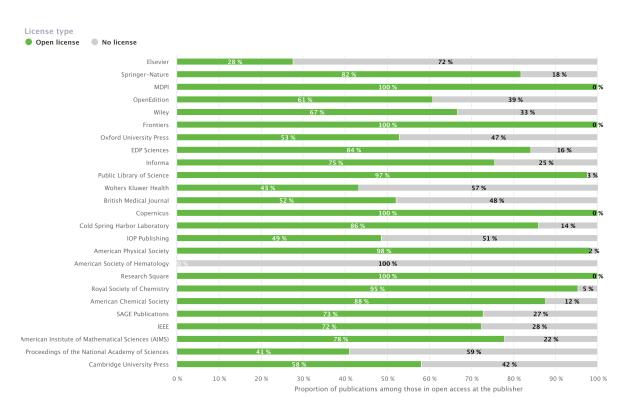


Figure 22: Rate of use of an open licence by the publishers or publishing platforms that distribute the most scientific publications in France in open access (top 25, 2020 publications)

should be weighed against other virtuous economic models - in particular the 'diamond 'model - which allows greater cost control and equity in access to publication for researchers.

The figure 23 shows the distribution of scientific publications in France released in 2020 and in open access by their publisher for a publication fee, according to the price applied (APC amount). Each point on a curve represents a volume of publications released for a given APC rate band. A distinction is made between the curve representing publications released in journals where all content is open access (Gold full APC) and the curve representing publications released in hybrid journals, where only part of the content is in open access while the rest is subject to subscription. It is possible to view the distribution for each publisher or publishing platform. When several publishers use the same publishing platform, the platform level has been privileged.

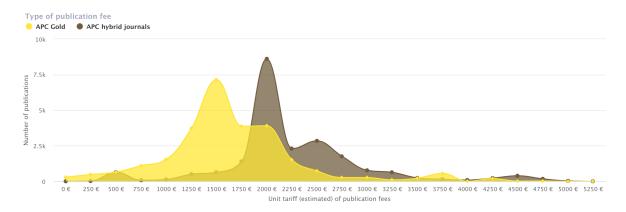


Figure 23: Distribution of scientific publications in France released in 2020 according to publication costs

## 3.1.4 Open repositories impact on the open access dynamics

The open repositories are open access platforms on which scientific publications are deposited, which can be consulted by anyone. They are most often powered by author deposit, but in some cases may be powered by the journal publishers themselves. Open archives perform different functions: they make articles published in subscription journals available in open access, they ensure the permanent preservation of scientific literature and facilitate the identification of the outputs of a laboratory or an institution. Several incentives have led to an increase in the number of French scientific publications deposited in an open archive. This is mandatory for publications from projects funded by the ANR since 2019. The barometer also counts the preprints servers among open archives, on which researchers deposit initial versions of their manuscripts to propose them for peer review, before formal submission to a journal.

For each year of observation since 2018, the graph represents the share of scientific publications in France released during the previous year that are available in an open archive. Some of these publications may be simultaneously made available in open access by their publisher. Thus, in 2021, 46% of scientific publications in France released in 2020 were available in an open archive (figure 24).

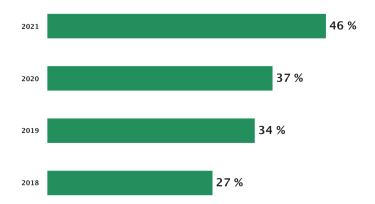


Figure 24: Rate of scientific publications in France available in an open archive by observation date

In the figure 25, for each observation date and by publication year, the rate of scientific publications in France that are available in an open archive. Each line represents the rates observed for an observation date and each rate is expressed as a function of the volume of publications published in the year observed. We observe that, for publications released during a given year, the availability rates in an open archive progresses from one observation year to the next. This is due to the fact that authors of publications progressively proceed to deposit them in an open archive, in particular when embargoes imposed by publishers have expired. Thus, between 2018 and 2021, the rate of publications published in 2017 that are available in an open archive has increased from 27% to 38%.

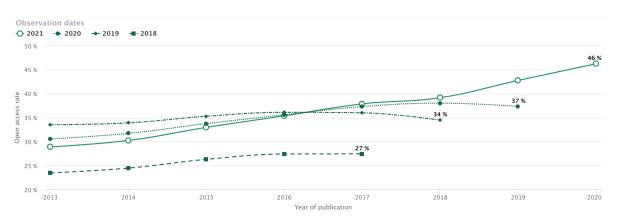


Figure 25: Evolution of the rate of scientific publications in France available in an open archive, by observation date

HAL, Pubmed Central, ArXiv and BioRxiv are the archives that hosted the most French publications in 2020. Several factors explain the choice by researchers of an open archive to deposit their publication. Some archives are references in a discipline (PubMed Central (PMC) for medical research), others are focused on the scientific production of a country (HAL for France). A single publication can be deposited simultaneously in several open archives. The deposit in open archives of foreign research institutions is due to the presence of co-authors who are affiliated with them.

The figure 26 indicates which are the most used open archives hosting scientific publications in France published in 2020, specifying for each the number of publications concerned. When the same publication is deposited on several open archives, it is counted several times. In particular, it can be seen that HAL hosts 37,335 publications within the scope in 2020. The open archive HAL (all disciplines) is thus the main open archive used for scientific publications in France, well ahead of PubMed Central (biomedicine), arXiv (physics, mathematics and computer science) and bioRxiv (biology).

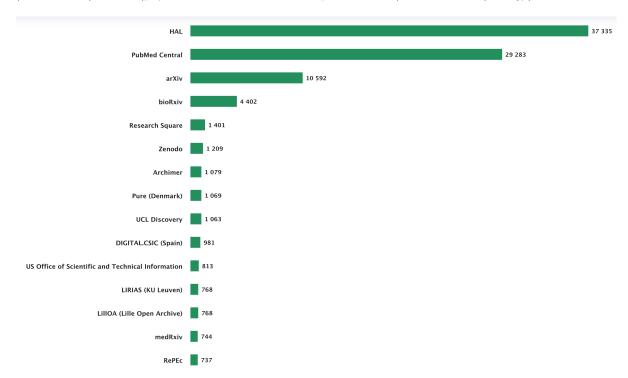


Figure 26: Main open archives hosting scientific publications in France published in 2020

HAL is a multidisciplinary open archive that hosts mostly French scientific publications (at least one France-based author)- although its scope is not limited to them. It is intended to play the role of a national archive for French research, guaranteeing both free access to scientific publications and their preservation. However, HAL is not the only open archive used by French researchers: depending on their institutional context or their disciplinary practices, they may prefer to deposit on other platforms, in particular when they have a global disciplinary audience. Therefore, the setting up of processes allowing to reference and to integrate in HAL French scientific publications deposited on other open archives is an important development axis.

HAL is the main open archive used to open French scientific publications. The figure 27 indicates among the scientific publications in France available on an open archive, the proportion of those available on HAL, by year of publication, as observed in 2021. We see in particular that among the scientific publications in France released in 2020 and opened on an archive, 48% are available on HAL (and thus 52% are not available on HAL but on at least one other archive or preprint server).

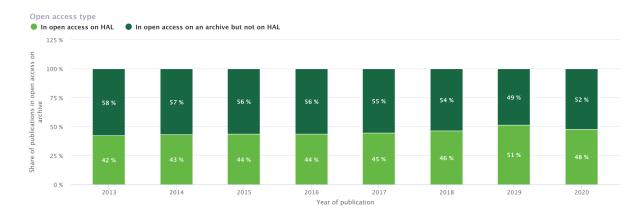


Figure 27: HAL coverage rate on scientific publications in France available in an open repository

## 3.2 Open access in France in the biomedical field

All the above indicators are detailed for the biomedical field. We simply apply the same computations rules on the publications that are indexed in PubMed.

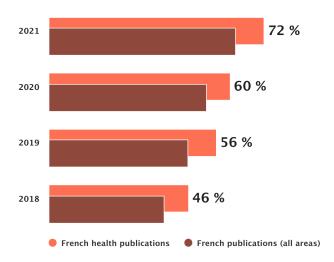


Figure 28: Open access rate of scientific publications in France in health published during the previous year by observation date

## 3.3 Clinical trials transparency in France

The clinical trials are research conducted on human beings, involving an intervention other than their usual care (delivery of a drug, use of a medical device, surgical act, etc.) in order to develop biological or medical knowledge. The lead sponsor of a clinical trial, who initiates, finances and supervises its conduct, may be a public or private organization: a health institution, a research organization, a pharmaceutical company, a medical device manufacturer, etc. The Open Science Barometer takes into account French clinical trials, i.e. those in which at least one of the participating institutions is located in France.

The registration of clinical trials and their results in public databases contributes to greater transparency in medical research. It allows a rapid circulation of results, even when these have been unsuccessful and

are not the subject of a scientific publication. It avoids the duplication of trials, verifies the methodology used and increases the confidence of the patients involved. It also attests to the proper use of funds allocated to medical research. The World Medical Association's Declaration of Helsinki, which defines the ethical principles applicable to medical research involving human subjects, establishes since 2008 that all clinical trials should be registered in a public database before the first patient is enrolled and that the results should be made public. These principles have also been supported since 2006 by the World Health Organization. Registries exist to carry out these registrations: ClinicalTrials.gov, an American registry that lists many studies conducted outside the United States, and the EU Clinical Trials Register in the European Union. Other registries exist but are not taken into account here because of their much lower use. In EU countries, the reporting of the results of clinical trials involving drugs within 12 months of their completion was made mandatory by a 2014 regulation, which came into force on January 31, 2022, the date the Clinical Trials Information System (CTIS) became operational. This requirement does not apply to non-drug clinical trials. The analyzes presented do not take into account clinical trials that are not registered in a public registry, the number of which is not known. The registration of clinical trials in a public registry should not be confused with prior declarations made to the competent authorities, such as ethics committees, to obtain authorizations to conduct these trials. These are not public.

The figure 29 represents, for all clinical trials conducted in France that have been registered and reported as completed in a public registry since 2010, those for which results have been communicated in this same registry. This communication may take the form of a compilation of the results obtained (we speak of "posted" results), a scientific publication (we consider them "published" results) or both. We do not introduce any hierarchy between posted results and published results. In both cases, they are considered as results communication. The graph distinguishes between clinical trials which sponsor is an industrial company (industrial sponsor) and those whose sponsor is a public research institution (academic sponsor). The graph does not take into account clinical trials that are not registered in a public registry. In France, the share of completed clinical trials that have posted and/or published results of publications is estimated at 57%. Industrial sponsors have much more systematic practices of transparency of their results (76%) while public sponsors share their results much less (31%).

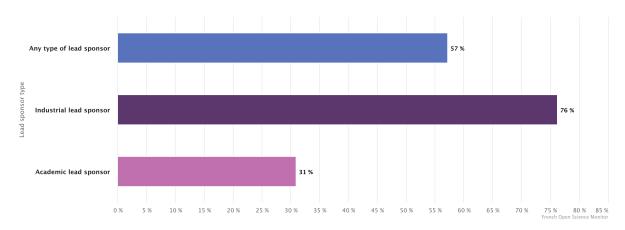


Figure 29: Share of registered and completed clinical trials that have posted or published results

The figure 30 must be read from left to right. It presents, for all clinical trials conducted in France that have been registered and reported as completed in a public registry since 2010, those for which a result has been posted or published. When a result has been reported, the graph distinguishes between those that are published in a peer-reviewed scientific publication. Finally, when a publication is mentioned, it specifies whether or not it is available in open access.

The World Medical Association (WMA)'s Declaration of Helsinki (Association (n.d.)) states that the

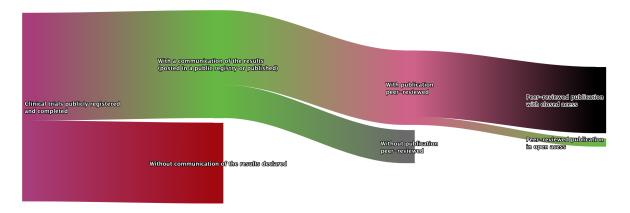


Figure 30: Distribution of clinical trials by results reporting

dissemination of results from medical research involving human beings, is an ethical obligation for all those involved, whether researchers, sponsors or publishers of scientific journals. Indeed, it appears to be a necessary counterpart to the involvement of patients in such research and as a major scientific and public health issue. The dissemination of results may take the form of an article in a scientific journal (published results) or a summary in a clinical trial register (posted results). This second vector ensures that the results of negative or inconclusive clinical trials, which are difficult to value in a scientific publication, are made public and properly disseminated. They are indeed valuable scientific contributions and the trials from which they result should not be ignored or unnecessarily duplicated.

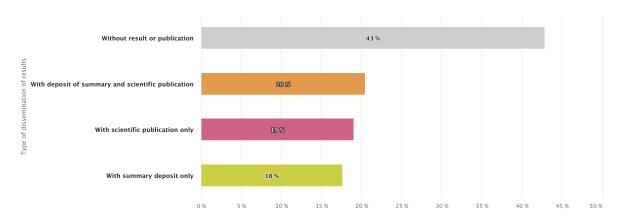


Figure 31: Procedures for reporting the results of completed clinical trials

Responsible sharing of individual data from clinical trials is a major challenge for the scientific community: sharing these data allows great transparency and maximizes the value of the data collected with the realization: • of re-analyzes with the aim of verifying the conclusions of the trials, • secondary analyzes exploring new research questions based on existing data, • meta-analyzes on individual data which, by pooling different studies exploring the same question, make it possible to provide the most precise answer possible. The International Committee of Medical Journal Editors (ICMJE) has stated that the responsible sharing of clinical trial data is ethically justified (Zarin et al. (2017)): since research subjects are willing to take risks for uncertain individual benefits, they expect the best possible use of the data collected, while minimizing the risk of re-identification. The ICMJE therefore requires that a data sharing statement specifying the terms of any sharing be included in each publication from July 1, 2018, and that it be specified in advance during clinical trial registration from January 1, 2019. At this

point, data sharing is recommended by the ICMJE but is not a requirement.

The figure 32 shows the number of registered clinical trials with and without individual data sharing statements by year since 2010. There has been a slow increase in the use of this instrument: 4% in 2010 and 17% in 2021.

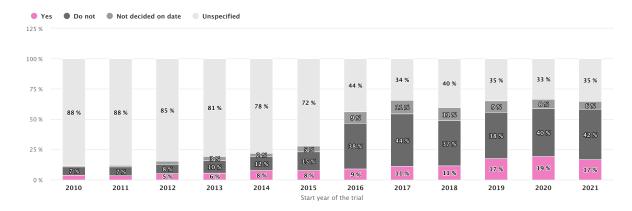


Figure 32: Distribution of registered clinical trials by presence of a data sharing statement

Observational studies are research studies conducted on human beings that do not involve any intervention other than their usual care, for example by questionnaires, cohort studies, etc. The legislation does not make it compulsory to publish the results of observational studies. However, a prior registration and systematic publication of the results of observational studies, on the same model as clinical trials, is a good practice that we are trying to measure. For the current version of the barometer, we work only on observational studies registered on the ClinicalTrials.gov or EU Clinical Trial Register platforms, with a methodology comparable to the one used for the clinical trials barometer. However, our object of study is different and more difficult to capture as many observational studies are not registered on these platforms. These results shall therefore be analyzed with caution.

As with clinical trials, the registration of studies and publication of their results is an important contribution to open science.

For this edition of the monitor, we estimate that 23% of observational studies publish results, with greater transparency from industrial sponsors (39%) than from public sponsors (17%).

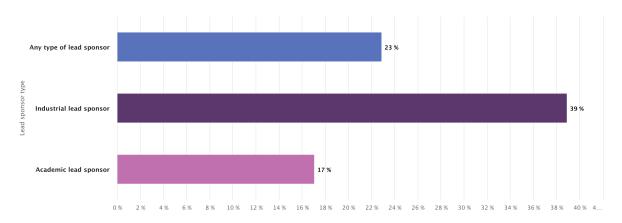


Figure 33: Share of registered observational studies reporting results between 2010 and 2020

#### 3.4 Limitations and future research

#### 3.4.1 Limitations

The main limitation of the current approach for the publications is the restriction to Crossref DOI. Indeed, we know it hides a fraction of the publications, especially in the Humanities, Social sciences and Computer sciences. This limitation is due to the fact that we need, first, to use identifiers to count the lowest number of duplicates possible in the monitor. Introducing Crossref-DOI-less entities would imply to set up a proper methodology to remove potential duplicates. On top of that, we would need an exteended OA discovery tool, as Unpaywall only focuses on Crossref DOI. Ideally, we would also wish to have past snapshots of this extended tool to be able to keep on producing a dynamic analysis of the open access trends.

Another limitation of the current approach is that we mix up preprint servers and open repositories. Both of them host open access version of articles, but they play very different roles in scholarly communication. Moreover, the monitor does not currently account for potential links between preprint and published article. So, an article with a preprint with a crossref DOI d1 and then published with another DOI d2 will actually counts twice in the current methodology. However, this phenomenon remains very limited as preprints represent less than 3% of the publications in the monitor database, especially because of the crossref DOI restriction. arXiv announced they will set DOI on their documents, but it will be Datacite DOI and not Crossref DOI.

## 3.4.2 Future work and local implementation

A new generation of French Open Science Monitor is being developed in order to integrate new research output to go beyond publications and clinical trials. In particular, we are working on research data and softwares. This project is led by the University of Lorraine, the French Ministry of Higher Education, Research and Innovation, and Inria and is supported by the European Union.

The current national-level Open Science Monitor has already been adapted to the level of an higher education and research institutions. To date, some twenty higher education and research institutions have already used it to obtain reliable and open indicators on the progress of open science in their academic production.

# Software and code availability

The source code used for the French Open Science Monitor is available on GitHub, and shared with an open licence. The code is split in modules for harvesting and parsing https://github.com/dataesr/h arvest-pubmed and https://github.com/dataesr/bso-parser-html, country and affiliation matching https://github.com/dataesr/matcher, discipline inference https://github.com/dataesr/scientific\_tagger, indicators computations https://github.com/dataesr/bso-publications and https://github.com/dataesr/bso-clinical-trials and the web user interface https://github.com/dataesr/bso-ui.

# Data availability

The data resulting of this work is shared on the French Ministry of Higher Education, Research and Innovation open data portal: https://data.enseignementsup-recherche.gouv.fr/explore/dataset/open-access-monitor-france/information/ and https://data.enseignementsup-recherche.gouv.fr/explore/dataset/barometre-sante-de-la-science-ouverte/information/.

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## References

- Arrizabalaga, Olatz, David Otaegui, Itziar Vergara, Julio Arrizabalaga, and Eva Méndez. 2020. "Open Access of COVID-19-Related Publications in the First Quarter of 2020: A Preliminary Study Based in PubMed." F1000Research 9 (August): 649. https://doi.org/10.12688/f1000research.24136.2.
- Association, World Medical. n.d. "The World Medical Association-WMA Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects." Accessed April 20, 2022. https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/.
- Bosman, Jeroen, Jan Erik Frantsvåg, Bianca Kramer, Pierre-Carl Langlais, and Vanessa Proudman. 2021. "OA Diamond Journals Study. Part 1: Findings." Zenodo. https://doi.org/10.5281/ZENO DO.4558703.
- Bracco, L. 2022. "Mesurer L'ouverture de La Science : Le Cas de L'Université de Lorraine." Revue Française Des Sciences de L'information et de La Communication, no. 24 (January). https://doi.org/10.4000/rfsic.12474.
- Bracco, Laetitia. 2020. "Baromètre Lorrain de La Science Ouverte." Université de Lorraine. https://hal.univ-lorraine.fr/hal-03450104.
- COSO, French Open Science Committee. 2018. "Feedback on EC Open Science Monitor Methodological Note." https://www.ouvrirlascience.fr/feedback-ec-science-monitor/.
- Goldacre, Ben, Nicholas J DeVito, Carl Heneghan, Francis Irving, Seb Bacon, Jessica Fleminger, and Helen Curtis. 2018. "Compliance with Requirement to Report Results on the EU Clinical Trials Register: Cohort Study and Web Resource." BMJ, September, k3218. https://doi.org/10.1136/bmj.k3218.
- Jeangirard, E. 2019. "Monitoring Open Access at a National Level: French Case Study." In *ELPUB* 2019 23d International Conference on Electronic Publishing. OpenEdition Press. https://doi.org/10.4000/proceedings.elpub.2019.20.
- Jeangirard, Eric. 2021. "Content-Based Subject Classification at Article Level in Biomedical Context." arXiv:2104.14800 [Cs], May. http://arxiv.org/abs/2104.14800.
- Joulin, Armand, Edouard Grave, Piotr Bojanowski, and Tomas Mikolov. 2016. "Bag of Tricks for Efficient Text Classification." arXiv:1607.01759 [Cs], August. http://arxiv.org/abs/1607.01759.
- Laakso, Mikael, and Bo-Christer Björk. 2013. "Delayed Open Access: An Overlooked High-Impact Category of Openly Available Scientific Literature." *Journal of the American Society for Information Science and Technology* 64 (7): 1323–9. https://doi.org/10.1002/asi.22856.
- Larivière, Vincent, Stefanie Haustein, and Philippe Mongeon. 2015. "The Oligopoly of Academic Publishers in the Digital Era." *PLOS ONE* 10 (6): e0127502. https://doi.org/10.1371/journal.pone .0127502.

- L'Hôte, Anne, and Eric Jeangirard. 2021. "Using Elasticsearch for Entity Recognition in Affiliation Disambiguation." arXiv:2110.01958 [Cs], October. http://arxiv.org/abs/2110.01958.
- MESRI. 2018. "National Plan for Open Science." https://cache.media.enseignementsup-recherche.gouv.fr/file/Recherche/50/1/SO\_A4\_2018\_EN\_01\_leger\_982501.pdf.
- ——. 2021. "2nd National Plan for Open Science." https://cache.media.enseignementsup-recherche.gouv.fr/file/science\_ouverte/20/9/MEN\_brochure\_PNSO\_web\_1415209.pdf.
- Piwowar, Heather, Jason Priem, Vincent Larivière, Juan Pablo Alperin, Lisa Matthias, Bree Norlander, Ashley Farley, Jevin West, and Stefanie Haustein. 2018. "The State of OA: A Large-Scale Analysis of the Prevalence and Impact of Open Access Articles." *PeerJ* 6 (February): e4375. https://doi.org/10.7717/peerj.4375.
- Pölönen, Janne, Mikael Laakso, Raf Guns, Emanuel Kulczycki, and Gunnar Sivertsen. 2020. "Open access at the national level: A comprehensive analysis of publications by Finnish researchers." *Quantitative Science Studies* 1 (4): 1396–1428. https://doi.org/10.1162/qss\_a\_00084.
- Waltman, Ludo, Stephen Pinfield, Narmin Rzayeva, Susana Oliveira Henriques, Zhichao Fang, Johanna Brumberg, Sarah Greaves, et al. 2021. "Scholarly Communication in Times of Crisis: The Response of the Scholarly Communication System to the COVID-19 Pandemic." Research on Research Institute. https://doi.org/10.6084/M9.FIGSHARE.17125394.V1.
- Zarin, Deborah A., Tony Tse, Rebecca J. Williams, and Thiyagu Rajakannan. 2017. "Update on Trial Registration 11 Years After the ICMJE Policy Was Established." New England Journal of Medicine 376 (4): 383–91. https://doi.org/10.1056/NEJMsr1601330.