

Data sharing 3 years on – from baby to toddler...

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ABSTRACT

At PhUSE 2013, I presented “A perspective on data transparency – the journey so far and where’s next?”. Back then, data transparency in pharma was in its infancy and we were taking baby steps. Fast forward to 2016, I reflect on my thoughts and predictions from 2013, outlining what has changed in pharma and the external environment, how data sharing has matured and what the next few years may hold.

Data sharing is a topic which is here to stay and is gradually becoming the norm. Initiatives continue to make data more accessible to researchers, whilst protecting patient privacy and ensuring data security. This includes efforts to ensure that all clinical trial sponsors are able to share data in a cost effective manner with the right incentives. Improved discoverability, curation and access to existing data sources and integrated ‘data access thinking’ are becoming increasingly important to the success of the pharma industry.

INTRODUCTION

The general topic of data transparency, including posting of protocol and results information to registries such as ClinicalTrials.gov and publications is not a new one. The sharing of patient-level data or PLD, however, is still a relatively novel concept in the pharmaceutical industry. Back in 2012/2013, high profile examples of lack of transparency were in the media; the European Medicines Agency (EMA) were facilitating discussions with industry and other stakeholders over their proposed transparency policy to include PLD access. The pharma industry was discussing what previously seemed like the unthinkable: making their PLD available to any requester with a meritorious research request.

During 2013 I presented on the topic of data sharing at the PhUSE Single Day Event in Basel and the Brussels annual conference [1], with a focus on PLD sharing. At that time, the topic seemed to generate interest and scepticism in equal measure. In this paper I will reflect on my thoughts and predictions from 2013, in particular whether the opportunities and challenges identified have proven to be true.

I will then go on to outline what has changed since 2013, in both the pharma industry and the external environment. In particular, I will reflect on how PLD sharing in particular as an overall topic has matured. The paper concludes with my thoughts on what the next few years may hold, and how integrated ‘data access thinking’ up-front could contribute to faster drug approval.

This paper provides an overview of the broad topic of data transparency, including registration and reporting of clinical trial results e.g. registries, publications as well as access to PLD. Some sections focus more heavily on PLD sharing. Topics such as EMA transparency policy 0070 blur the edges between release of PLD and release of clinical reports containing patient-level information. I will outline why all aspects of data transparency, including PLD access, need to be considered as the norm.

For the purposes of this paper, I have defined PLD as electronic copies of individual patient level data. This is standardly captured as SAS datasets within clinical trial processes and includes datasets representing the raw data (as recorded for the patient) and derived data (clinical endpoints calculated using results across a number of visits and/or assessment types) e.g. CDISC SDTM and ADaM datasets.

DATA TRANSPARENCY IN 2013



A perspective data transparency – the journey so far and where’s next?
PhUSE October 2013

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Whilst my PhUSE 2013 conference presentation [1] focused on access to patient-level data from clinical trials, in reality, pharma companies had been required to share data for a long time:

PhUSE 2016

- **2000:** ClinicalTrials.gov was launched as a national clinical trial registry by the US National Institutes of Health and in 2007, mandated posting of summary results within 12 months of trial completion [2]
- **2005:** ICMJE (International Committee of Medical Journal Editors) implemented a requirement that in order to publish data for any study, registration was required on a publicly available database [3]
- **2006:** World Health Organization (WHO) mandated registration of clinical trials [4]
- **2008:** Declaration of Helsinki amended to require that "Every Clinical trial must be registered in a publicly accessible database before recruitment of the first subject." [5]

During 2012-13, EMA initiated a number of working groups on data transparency [6] and proposals for new regulations. There were increasing calls for greater transparency from the media and campaign groups such as BMJ OpenData [7] and AllTrials [8]. There were high profile cases such as Roche (Tamiflu) [9] and AbbVie (Humira) [10] who filed a lawsuit challenging EMA's position to publish all clinical and preclinical data. Many pharma companies were developing their own data transparency policies and clarifying existing commitments. In particular Roche published its data sharing policy [11], focusing on reaffirming two existing commitments (publications in peer reviewed journals and posting protocol and summary results information to registries) and two new commitments (access to documents and patient-level data).

Pharma companies and industry bodies were continuing to develop their policies and strategies on the topic.

OPPORTUNITIES AND CHALLENGES

The following opportunities and challenges, regarding access to PLD, were identified during my PhUSE 2013 conference presentation [1]:

Opportunities:

- Increase scientific community's understanding of successful and failed medicines and related data
 - provide directions for drug discovery and development
 - more efficient and effective future clinical trials
 - analyses across treatments to inform safety and efficacy
- More collaboration between research groups and companies
- Promote Public Trust

Challenges:

- Users misunderstanding the data and/or analyses
 - erroneous conclusions
 - time lost re-analysing and correcting external requesters work
 - health scares
- Resource implications of redacting CSRs, generating anonymized datasets, supporting requesters
- Mature products - locating data, informed consent

In the next section I provide an overview of the numerous developments since 2013 as well as a reflection to what extent these opportunities and challenges have proven to be true.

WHAT HAS CHANGED SINCE 2013?

There have been unprecedented developments in the area of patient-level data sharing over the past few years. This is both in terms of ability of researchers to find and access clinical trial PLD, regulations with new transparency requirements for industry, numerous examples of cross-pharma collaboration to solve new challenges, initiatives to improve data transparency across all clinical trial sponsors (pharma, charities, academia etc.) and new vendors and tools. More specifically, many groups have been looking to develop best practices on how to effectively de-identify and anonymise PLD for external sharing. All of these aspects and more are reflected in the discussion below.

Finally, this section also provides a reflection the extent to which opportunities and challenges identified in 2013 have proven to be true and the degree to which data transparency is becoming an integral part of what we do to conduct and report clinical trials.

PHARMA REQUEST SITES

During 2013-15, many pharma companies either developed their own or became part of consortium-led request sites which enabled external researchers to browse studies available and request access to PLD. This section provides a brief overview.

ClinicalStudyDataRequest.com or 'CSDR' [12]



In January 2014, ClinicalStudyDataRequest.com or 'CSDR' was launched. This is a multi-sponsor patient-level data request site. The original concept was based on a GSK-only request site which was expanded to accommodate additional sponsors, in theory both commercial and non-commercial (academics, charities etc.). The website allows external researchers to browse studies listed as available to request, put together a research proposal and submit. It also allows researchers to enquire about studies not listed as to whether they could be available to request. The research proposal requires information such as lay summary of the research intent, study design, studies required and rationale, primary and secondary endpoints, statistical analysis and publication plans. It also accommodates requests for studies from different sponsors as part of a single request.

Following submission, the research proposal is initially triaged by the IRP Secretariat, run by the Wellcome Trust [13]. The Wellcome Trust are a UK-based global medical charity. Following sponsor feasibility checks, the Independent Review Panel (IRP) approve or decline the request. Following approval, sponsors prepare anonymised PLD and redacted documents for sharing via the secure SAS-hosted CTDT MSE portal [14]. In this portal, researchers have access to the data as well as analytical tools such as SAS and R, with controls on download of PLD.

Since its inception, there have been a number of changes:

- the number of sponsors growing to thirteen;
- the Wellcome Trust taking over the secretariat function in 2015 and appointing a new IRP (new panel members);
- appointing a new independent chair of the CSDR steering committee (3Q16);
- discussions with non-commercial, academic groups with a view to them joining (in line with the stated long-term aim of the request site);
- the original IRP members will publish an article later in 2016 providing an overview of PLD requests via CSDR [15]. The article provides insight into volume of requests, primary purpose of those requests, statistical methods, and common disease areas:
 - 177 research proposals were submitted between May 7, 2013 and November 14, 2015.
 - The primary purpose of the proposals was a new study and publication (148), with confirmation of results being quite uncommon (3).
 - Statistical methods ranged widely and included predictive models (63), meta-analysis (28), survival analysis (15), and novel analysis methods (14).
 - The most common content areas were cancer (34), cardiovascular disease (21), asthma and COPD (13), and HIV (8).

More information on the process, including the criteria used by the IRP for assessing research proposals, can be found on the CSDR website. The website also has metrics on number of requests and statuses throughout the request process.

Yale Open Data Access or 'YODA' [16]



The YODA website states: "The YODA Project seeks mutually beneficial partnerships with Data Holders, promoting independence, responsible conduct of research, good stewardship of data, and the generation of knowledge in the best interest of society. To participate, each Data Holder must transfer full jurisdiction over data access to the YODA Project".

Johnson and Johnson (J&J) have been in partnership with YODA since October 2014. YODA performs the independent scientific reviews of research requests (requests for both PLD and reports) and as such makes all decisions on release of clinical trial data.

Examples of other pharma request sites

Many other pharma companies have their own request sites, a few examples are listed here: Pfizer [17], MSD [18], Amgen [19], Astra Zeneca [20].

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Many include similar aspects to CSDR and YODA such as certain in-scope criteria for availability of studies, an (independent) panel review, signed legal agreement and secure sharing of anonymised data and documents. In some cases independent panel reviews are only utilised if the sponsor rejects the request.

REGULATORS AND REGISTRIES

Sharing of PLD needs to be seen in the context of the wider data transparency piece. For example, in order for researchers to develop a research proposal for accessing PLD, it is important that adequate information is first available via registries. In addition, first accessing the CSR, prior to PLD request, may also lead to a better informed PLD research proposal. One concept has been coined 'discoverability' – the ability of researchers to know about the existence of clinical trials and then where to go to access further data from those studies.

There are numerous aspects of regulatory policies and directives, particularly at EMA, which incorporate data transparency elements. These include:

EMA policy on access to documents (policy 0043) has been in force since 2010 [21] and requires sponsors to provide redacted copies of regulatory documents on request, via the EMA;

EMA Clinical Trial Regulation, coming 2018, incorporates elements of trial disclosure, such as lay summaries aimed at the general public which may include trial participants [22];

EMA transparency policy 0070 was published October 2014, [23] and guidance published March 2016 [24]. The policy entered into force start of 2015 and applies to clinical reports contained in all marketing-authorisation applications since then. The first reports are currently foreseen to be publicly available in September 2016. For phase I of the policy, it requires anonymised copies of reports to be provided to EMA within a certain timeframe following CHMP opinion, for onward publication to the general public. One major challenge is that reports will be published including case narratives, effectively patient-level information, which are challenging to sufficiently anonymise in order to protect patient privacy whilst retaining data utility.

Two notable clinical trial registries are in US and EU:

'**EudraCT**'- European Union Drug Regulating Authorities Clinical Trials, [25] is the European Clinical Trials Database of all clinical trials of investigational medicinal products with at least one site in the European Union commencing 1 May 2004 or later. Posting of clinical trial summary results to EudraCT became mandatory July 2014;

ClinicalTrials.gov

A service of the U.S. National Institutes of Health

ClinicalTrials.gov [2] – A 'NPRM' or 'Notice of Proposed Rule-Making' expanded the requirements for submitting clinical trial information to the ClinicalTrials.gov database in 2016. One element relates to 'Available Study Data/Documents' for sponsors to outline study data sets and documents that are being shared for that particular clinical trial.

INDUSTRY INITIATIVES

The area of clinical trial data transparency has resulted in considerable cross-sponsor collaboration. Between pharma, it can be considered as a topic in the 'pre-competitive space' (i.e. areas of business where we do not compete but collaborate).

Several groups have been looking to develop best practices on how to effectively de-identify and anonymise PLD for external sharing, including developing capabilities regarding quantification of the risk of patient re-identification. Scenarios include both sharing of PLD with specific external researchers in a secure and controlled manner e.g. CSDR [12] as well as sharing of patient-level information contained within reports e.g. in the form of case narratives e.g. EMA policy 0070 [24].

Some of these initiatives/publications are outlined below:



EFPIA-PhRMA issued the 'Joint EFPIA-PhRMA Principles for Responsible Clinical Trial Data Sharing' in 2014 [26]. It stated that "Biopharmaceutical companies are committed to enhancing public health through responsible sharing of clinical trial data in a manner that is consistent with the following principles:

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



PhUSE Data Transparency working group "collaborated to define a set of rules built around the CDISC SDTM standards to provide the industry with a consistent approach to data de-identification and increase consistency across anonymized datasets." They are now working on solutions for CDISC ADaM standards and EMA policy 0070 [27];

TransCelerate has several working groups in the area of Data Transparency and has published several documents [28]:

- Recommendations for Drafting Non-Promotional Lay Summaries of Clinical Trial Results
- Clinical Study Reports Approach to Protection of Personal Data
- Data De-identification and Anonymization of Individual Patient Data in Clinical Studies – A Model Approach



EFSPi and PSI (European Federation of Statisticians in the Pharmaceutical Industry and Statisticians in the Pharmaceutical Industry) published a series of articles with intent of providing knowledge and insights regarding the practical challenges and opportunities of accessing clinical trial data for re-analysis or secondary scientific research purposes. [29]. The articles were:

- Statistical guidance for responsible data sharing: an overview
- Protecting patient privacy when sharing patient-level data from clinical trials (lead author: K. Tucker)
- Best practice for analysis of shared clinical trial data
- Accessing and working with pharmaceutical clinical trial patient level datasets – a primer for academic researchers
- Data sharing and the evolving role of statisticians

Project Datasphere is "an independent, not-for-profit initiative of the CEO Roundtable on Cancer's Life Sciences Consortium (LSC), operates the Project Data Sphere platform, a free digital library-laboratory that provides one place where the research community can broadly share, integrate and analyze historical, patient-level data from academic and industry phase III cancer clinical trials." [30]. This was one of the original cross-pharma data sharing initiatives.

OTHER INITIATIVES

Initiatives/publications not specific to pharma include:



The **Institute of Medicine (IOM)** published their report in 2015, 'Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk'. [31] "(The IOM) assembled a committee to develop guiding principles and a practical framework for the responsible sharing of clinical trial data. In its report...the committee concludes that sharing data is in the public interest, but a multi-stakeholder effort is needed to develop a culture, infrastructure, and policies that will foster responsible sharing—now and in the future."

The comprehensive report covers:

- Guiding Principles for Sharing Clinical Trial Data including key potential benefits and risks
- Roles and Responsibilities of Stakeholders
- Clinical Trial Lifecycle and When to Share Data, what Data Should Be Shared
- Governance
- The Future of Data Sharing in a Changing Landscape
- Appendix on Concepts and Methods for De-identifying Clinical Trial Data

Annals of Internal Medicine

EDITORIAL

Sharing Clinical Trial Data: A Proposal From the International Committee of Medical Journal Editors

The **ICMJE** (International Committee of Medical Journal Editors) in 2016 made a proposal for data to be made available in order to replicate results in publications [32]. ICMJE invited comment on their proposal that "As a condition of consideration for publication of a clinical trial report in our member journals, the ICMJE proposes to require authors to share with others the de-identified individual-patient data (IPD) underlying the results presented in the article (including tables, figures, and appendices or supplementary material) no later than 6 months after publication.";



The **MRCT** (Multi Regional Clinical Trials Center) are leading efforts to enable sharing and access to clinical trial data from all types of sponsors: academia, industry and not for profit sectors, via a new platform called 'Vivli'. [33]. "Vivli is a not-for-profit entity that will promote global clinical trial data sharing through the establishment of a data platform where data can be hosted, searched, and accessed. Vivli will build bridges to existing platforms to enable pooling of current datasets and key learnings from extant data sharing communities. We envision the platform to be used by researchers and sponsors from academia, industry, and the non-profit sectors."

TOOLS AND VENDORS

As the requirements for increased sharing of PLD and reports increases, so does the need for vendors and tools to support that work. New requirements have resulted in offerings in the areas of data de-identification and anonymisation, risk quantification, report redaction/anonymisation etc. Vendors include Privacy Analytics [34] (offering consultation, training, software tools etc.), D-Wise [35] (data de-identification tool 'Blur'), Business & Decisions Life Sciences [36] (data de-identification tool 'De-ID'), as well as vendors focusing more on the medical writing / reports side e.g. as required for EMA policy 0070 such as Synchrogenix [37].

EXPERIENCE TO DATE

This section provides a reflection on experience to date. As outlined above, we have seen unprecedented changes over the past 3-4 years and an increase in what is required of clinical trial sponsors in making trial information transparent. Numerous clinical study and other reports have been shared. Access has been provided to hundreds of trial datasets. To what extent is data transparency now just another element of what we do as pharma companies? To what extent have opportunities and challenges been realised?

Reflection on opportunities

In 2013, several opportunities were identified related to sharing of PLD (see earlier section 'Data Transparency in 2013'). In particular, increasing the scientific community's understanding of medicines, increased collaboration between research groups and companies, and promoting public trust. In an attempt to assess some of these points, I will reflect on Roche experience, in particular requests via the CSDR request site.

The reality is that the uptake of PLD requests, whilst a steady trickle, have not been at the level anticipated. For example, since launch of CSDR [12] in January 2014 until mid August 2016, Roche has received approximately 31 research proposal involving Roche studies, so a rate of about 1 per month (each research proposal may involve multiple studies). In reality, access to PLD for further research could be seen as a rather 'niche' research area, requiring specialist knowledge and expertise such as a statistical programming/biostatistics background. It could be that for many research areas, access to summary information in the form of a Clinical Study Report or CSR may suffice. None of those 31 Roche research proposals have yet reached publication stage. In fact, as a whole, very few CSDR requests have reached publication stage. Therefore it is too early to say if increased availability of access to PLD has resulted in an increase in the scientific community's understanding of medicines or a change in public trust.

Reflecting on Roche experience again, it is difficult to say if a renewed focus on access to PLD has resulted in increased collaboration between research groups and companies. Certainly as a company, Roche have defined new processes (outside of access via CSDR) which defines how molecule project teams can safely and securely share PLD with collaborating groups. We have seen an increase in requests for support for areas such as data sharing agreements and data anonymisation. Increasing numbers of strategic collaborations at Roche/Genentech (examples Human Longevity Inc.[38], Foundation Medicine [39]) are requiring sharing of increasing volumes of clinical trial PLD.

Reflection on challenges

Turning to the perceived challenges, to what extent have these been realised? One concern was users misunderstanding the data and/or analyses, resulting in erroneous conclusions, time lost correcting requesters work or health scares. Similar to the discussion above on opportunities, it is too early to know if these issues will arise as there have been so few publications to date. At Roche we have not had to spend time re-analysing or refuting incorrect conclusions. As well as it being early days in publications, another reason is that very few research proposals via CSDR have had the objective of re-analysing original trial results, the majority (>95%) being new secondary research. [15].

Another identified challenge was the resource implications of supporting all transparency activities. This is a concern which in my mind has proven to be true. In a large organisation (or indeed any sized organisation), ensuring that all clinical trials are registered and reported within the defined timeframes is a huge logistical challenge. Increasing requests for data and documents requires knowledgeable staff to respond to those requests. However, given that many data transparency activities increasingly relate to regulatory mandated activities, these resource implications need to be seen as an integral part of the drug development and marketing lifecycle.

The final challenge concerned locating data for mature products (i.e. trials that had been conducted over 10 years ago) and the informed consent forms (ICF) used in these historic trials. At Roche, we have not found either of these topics to be barriers to increased data access. Whilst PLD from older studies is not necessarily curated to the standard we would like, it has been feasible for our data sharing team to locate older datasets, using newly developed search tools and building up expertise. Our policy and process to anonymise data have meant that original informed consent wording has not proven to be an issue and in fact since mid 2013, our ICF has incorporated language specifically regarding the potential use of data for secondary research purposes.

Integrating data transparency activities

The requirement to register and report trials in registries, and provide access to PLD and documents is increasingly a given. The changing landscape means that transparency of data and reports should no longer be considered as a task to be 'bolted on', at the end of the study reporting process. Increased use of study-level and patient-level data standards across all clinical trial sponsors will aid these activities and increase the ability of secondary researchers to combine PLD across multiple sources. Strategies should be developed to integrate and automate activities to enable onward sharing of

both PLD and documents, including data anonymisation and risk assessment (e.g. quantifying the risk of patient re-identification). These activities could then facilitate 'voluntary' PLD sharing such as via CSDR [12], sharing of reports and PLD via EMA policy 0070 [23], [24]. In fact, this integrated approach will be aided by better planning at trial concept stage. This is in line with Institute of Medicine [31] recommendation that every trial should have a 'data sharing plan', where all downstream data sharing requirements can be identified and tracked.

Realising the potential of increased transparency

In addition to the requirements to provide access to data, increased data transparency can also bring benefits to clinical trial data holders and foster increased collaboration. We have access to numerous new sources of information and data. Additional scientific research stemming from PLD access may well benefit pharma companies in the longer run with increased understanding of diseases, endpoints or drug molecules. It may result in new opportunities to collaborate which previously did not exist.

In addition, our experience at Roche has been that external requirements are leading to a new understanding and focus on curation and accessibility of data assets for internal access e.g. improved sharing of data within the company. Overall, increased transparency is good for patients, society, scientific research and ultimately the pharma industry itself.

OPPORTUNITIES AND CHALLENGES FOR THE NEXT 3 YEARS?

Given the experience of the past few years, I've tried to identify what I see as three opportunities and challenges for the next three years in data transparency generally and PLD sharing specifically:

Opportunities:

- to increase external awareness of what data is available (inc. the types of information and where to find them), help people navigate to the right level of information (registry summary data, reports such as CSRs, PLD) and encourage researchers to see the potential in accessing PLD and reports
- to streamline PLD access to researchers (ease of access, analytical tools available etc.), increase capability to share across all types of data holders (e.g. to better facilitate requests such as meta-analyses)
- all to capitalise on this new unprecedented era of data availability

Challenges:

- to encourage and enable transparency across all types of clinical trial sponsors, (e.g. pharma, charities, academia)
- to develop capabilities and awareness of the need for data anonymisation/risk assessment, integrating these activities into processes, with increased automation, and linking of PLD to reports
- improved data curation and data integration strategies by all clinical trial data providers

DATA TRANSPARENCY IN 2019?

Pulling together all of my experience over the past 3-4 years in data transparency, here is my vision of data transparency in 2019:

- Continued explosion in data availability from different sources – genetic/genomic, real-world data, clinical trial data, data integration, iterative learning. All of these data sources increasingly coming together, we are already seeing this.
- An integrated portal for sharing of PLD from clinical trials from all type of data holders
- Data transparency activities 'baked in' to clinical trial processes. Planning future data sharing activities at trial start-up will move data sharing from being an afterthought at the end of the trial to just another element of drug development and introduce increased efficiencies. Integrated 'data access thinking' up-front could even contribute to faster drug approval. Sponsors could base clinical development thinking on a broader base of information and as a consequence take better, more informed decisions across the entire drug development journey. EMA transparency policy 0070 requires merging of expertise from medical report writing, disclosures and dataset anonymisation and puts transparency firmly on the critical path to approval.
- Improved 'discoverability', curation and access to existing data sources
- Increased use of existing data sources to design new clinical trials (e.g. as historical controls) resulting in streamlined and faster new trials as reduced need for recruitment of actual patients. Thoughtful re-use of existing data sources could result in some clinical trials not needing to be conducted or being smaller in size.
- Ongoing and increasing collaboration across companies and groups, both external and internally

CONCLUSION

Data sharing is a topic which is here to stay and should now be considered the norm. Initiatives will continue to make data more accessible to researchers, whilst protecting patient privacy and ensuring data security. This includes efforts to ensure that all sponsors of clinical trials are able to share data in a cost effective manner with the right incentives. Improved discoverability, curation and access to existing data sources and integrated 'data access thinking' are becoming increasingly important in the success of the pharma industry.

REFERENCES

- [1] <http://www.phusewiki.org/docs/Basel%202013%20SDE%20Presentations/A%20perspective%20on%20sharing%20of%20patient-level%20data.pdf>
- [2] <https://clinicaltrials.gov/>
- [3] <http://www.icmje.org/about-icmje/faqs/clinical-trials-registration/>
- [4] <http://www.who.int/mediacentre/news/releases/2006/pr25/en/>
- [5] <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2681053/>
- [6] http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000556.jsp
- [7] <http://www.bmj.com/open-data>
- [8] <http://www.alltrials.net/>
- [9] <http://www.bbc.com/news/health-22029708>
- [10] <http://www.reuters.com/article/us-pharmaceuticals-europe-abbvie-idUSKCN0YW1D6>
- [11] http://www.roche.com/roche_global_policy_on_sharing_of_clinical_study_information.pdf
- [12] <https://www.clinicalstudydatarequest.com/Default.aspx>
- [13] <https://wellcome.ac.uk/what-we-do/our-work/clinical-trials-data-sharing>
- [14] <http://www.phusewiki.org/docs/Conference%202014%20TT%20Papers/TT04.pdf>
- [15] Strom et al. 2016; 'Data Sharing: Is the Juice Worth the Squeeze?' In Press
- [16] <http://yoda.yale.edu/johnson-johnson>
- [17] http://www.pfizer.com/research/clinical_trials/trial_data_and_results
- [18] <http://www.msdrresponsibility.com/ethics-transparency/transparency-disclosures/>
- [19] <http://www.amgen.com/about/how-we-operate/policies-practices-and-disclosures/ethical-research/clinical-data-transparency-practices/>
- [20] <https://astrazenecagroup-dt.pharmacm.com/DT/Home/Index>
- [21] http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/11/WC500099473.pdf
- [22] http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000629.jsp&mid=WC0b01ac05808768df
- [23] http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/10/WC500174796.pdf
- [24] http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2016/03/news_detail_002481.jsp&mid=WC0b01ac058004d5c1
- [25] http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2016/03/news_detail_002481.jsp&mid=WC0b01ac058004d5c1
- [26] <http://efpia.eu/mediaroom/132/43/Joint-EFPIA-PhRMA-Principles-for-Responsible-Clinical-Trial-Data-Sharing-Become-Effective>
- [27] http://www.phuse.eu/Data_Transparency.aspx
- [28] <http://www.transceleratebiopharmainc.com/assets/clinical-data-transparency/>
- [29] <https://bmcmmedresmethodol.biomedcentral.com/articles/supplements/volume-16-supplement-1>
- [30] <https://www.projectdatasphere.org/projectdatasphere/html/home>
- [31] <http://www.nationalacademies.org/hmd/Reports/2015/Sharing-Clinical-Trial-Data.aspx>
- [32] <http://www.icmje.org/news-and-editorials/M15-2928-PAP.pdf>
- [33] <http://mrctcenter.org/projects/vivli/>
- [34] <http://www.privacy-analytics.com/>
- [35] <http://www.d-wise.com/blur-clinical-trial-data-de-identification>
- [36] <http://www.businessdecision-lifesciences.com/3474-de-id.htm>
- [37] <http://www.synchrogenix.com/>
- [38] <http://www.humanlongevity.com/human-longevity-inc-signs-agreement-with-genentech-for-whole-genome-sequencing-and-analysis-of-samples/>
- [39] <http://investors.foundationmedicine.com/releasedetail.cfm?releaseid=905240>

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See references.

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