



Transparency of Clinical Study Data Opportunities, Risks and Side-effects

SFdS Biopharmacie et Santé

23. 11. 2015

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- A brief history of clinical trial data transparency
- How the pharmaceutical industry is making clinical trial data transparent
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What's the issue ?

Half of all clinical trials
have never been published.

This is a scandal.

Sign the petition here:

www.alltrials.net

alltrials.org 2014-04-28

What's not the issue ?

Clinical trial registration and posting of summary results

- Mandatory in the US since 2005, EU since 2014
- Commitment by research manufacturers since 2005



Bayer HealthCare: Science For A Better Life
Pharmaceuticals

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Trial Finder - Clinical Trial Registry and Results Search

Search Phrase (in English) or Trial Number:
 » Search

You may leave this field empty, and use only the »Help search limitation options provided below.

Product: All	Country: All	Condition: All
Trial Status: All	Phase: All	Results Synopsis available (y/n): All

☒ Bayer HealthCare Pharmaceuticals trials
☐ All Bayer HealthCare trials (including Bayer HealthCare Pharmaceuticals trials)

» Clear » Search

<http://www.bayerpharma.com/en/research-and-development/clinical-trials/trial-finder/index.php> 2014-10-08



How it all began ...

In 2007, Danish researchers turned to EMA and requested access to clinical study reports.

EMA refused disclosure due to drug producers' commercial interests.

EU Ombudsman called on EMA to disclose the documents or provide a convincing explanation as to why no access could be given.

EMA decided to grant access to the documents requested.

EMA further committed itself to reactive disclosure.

www.ombudsman.europa.eu/en/cases/summary.faces/en/5646/html.bookmark accessed 2013-09-26

EMA's plan for proactive disclosure



Workshop November 22nd 2012

Advisory groups April 30th 2013

Draft EMA policy June 24th 2013

Consultation until September 30th 2013

- 1,138 comments submitted by 169 entities

Final EMA policy by
~~November 30th 2013~~

- October 2nd 2014

VIEWPOINT

Pharmaceutical
Statistics

(wileyonlinelibrary.com) DOI: 10.1002/pst.1603

Published online 18 October 2013 in Wiley Online Library

European Federation of Statisticians in the Pharmaceutical Industry's position on access to clinical trial data

Christine Fletcher,^{a*} Stefan Driessen,^b Hans Ulrich Burger,^c
Christoph Gerlinger,^{d,e} and Egbert Biesheuvel^f on behalf of the EFSPI

The European Federation of Statisticians in the Pharmaceutical Industry (EFSPI) believes access to clinical trial data should be implemented in a way that supports good research, avoids misuse of such data, lies within the scope of the original informed consent and fully protects patient confidentiality. In principle, EFSPI supports responsible data sharing. EFSPI acknowledges it is in the interest of patients that their data are handled in a strictly confidential manner to avoid misuse under all possible

What shall be disclosed (according to EMA's draft policy)



Full overviews, clinical summaries, and study reports (text, tables, figures)

- For unrestricted download
- Redacted (e.g., case narratives)
- Without some of the appendices (e.g., individual patient data listings)

Patient level data

- De-identified for restricted download
- With (minimal) prior data sharing agreement





New approach by EMA

EMA held closed door stakeholder meetings in May 2014

For now only clinical study reports (CSR)

- CSRs (Module 5) + Clinical Overviews (Module 2.5) + Clinical Summaries (Module 2.7) + Appendices to CSRs No. 16.1.1, 16.1.2 and 16.1.9
- Controlled access to CSR (read on screen only)
- Contract between EMA and requestor
- Strengthened redaction principles
 - E.g. redact exploratory variables unrelated to regulatory decision (!)

Individual patient data (IPD) will be discussed with stakeholders later



Hot debate ongoing

BMJ editorial: “The European Medicines Agency gets cold feet at the last minute”

BMJ 2014;348:g3561

IQWiG letter to BMJ: “**EMA’s transparency policy: A placebo intervention?**”

www.bmj.com/content/348/bmj.g3432?tab=responses

EMA press release: “European Medicines Agency agrees policy on publication of clinical trial data with more user-friendly amendments”

www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/06/news_detail_002124.jsp

Final EMA policy

Released October 2nd 2014

Effective: new application: Jan 1st 2015
extension of indication: Jul 1st 2015

Scope: centralized procedure only (!)

Overviews, summaries and reports

- Redacted for data protection and commercial confidential information
- Redaction checked by EMA
- Publication after end of procedure

View on screen for all

Download for academia, HTA bodies

- With proper identification only



Release of patient level data postponed

Only data held by EMA (!)

Stakeholder discussion planned

Revision of policy thereafter

Industry commitment



European Federation of Pharmaceutical
Industries and Associations

Responsible Transparency

The EFPIA Code | Codes of Conduct | Clinical Trials | **Responsible Data Sharing** | Media | Downloads | Search... >

[Home](#) / Responsible Data Sharing

Responsible Data Sharing

On July 24, EFPIA and PhRMA formally launched their Joint Principles for Responsible Clinical Trial Data Sharing to Benefit Patients.

This commitment to data sharing will enhance research and scientific knowledge, advance patient care and improve public health. Under the Principles, biopharmaceutical companies will dramatically increase the amount of information available to researchers, patients, and members of the public. The full Commitments can be found [here](#).

Download




Principles for
Responsible Clinical
Trial Data Sharing
239.13 kB

transparency.efpia.eu/responsible-data-sharing (accessed 2014-02-14)



How data is made available



Registered Users, Please [Login](#)

HOME | STUDY SPONSORS | STEP BY STEP | MY REQUESTS | LOGIN OR CREATE AN ACCOUNT | METRICS | HELP

About

This site	Next steps
<p>Access to clinical trial data provides opportunities to conduct further research that can help advance medical science or improve patient care. This helps ensure the data provided by research participants are used to maximum effect in the creation of knowledge and understanding.</p> <p>Researchers can use this site to request access to anonymised patient level data and/or supporting documents from clinical studies to conduct further research.</p>	<p>Study sponsors who have committed to use this site are Astellas, Bayer, Boehringer Ingelheim, Eisai, GSK, Lilly, Novartis, Roche, Sanofi, Takeda, UCB and ViiV Healthcare.</p> <p>Other clinical trial sponsors and funders are invited to join with the aim of transitioning to a fully independent system which allows access to data from clinical trials conducted by multiple companies and organisations. It is hoped that such a system will be put in place as soon as possible.</p> <p>If you are a study sponsor interested in listing studies on this site, contact information is provided here.</p>

www.clinicalstudydatarequest.com 2015-11-04



How data is made available

View available clinical studies

Scroll down the list of studies provided below. Studies are listed by study medicine in alphabetical order. Alternatively you can browse the list of studies using the search function.

To select studies and submit a research proposal or enquiry, go back to the Home page and select View and submit.

This takes you back to the previous page to enable you to view studies from a specific sponsor.

View studies from a specific sponsor

Select medicine, medical condition or phase from the drop down boxes. This searches all the available clinical studies. Selecting from more than one drop down box will "and" the criteria.

Find by:

Select Medicine...

Select Medical Condition...

Select Phase...

2760+ studies already available (Nov 2015)

clinicalstudydatarequest.com 2015-11-04



How data is made available

How it works

Submission

Researchers can submit research proposals and request anonymised data from clinical studies listed on this site. Study sponsors will add more studies when the site is updated.

Information on sponsor's criteria for listing studies and other relevant sponsor specific information is provided in the [Study sponsors section](#) of this site.

Researchers can also submit enquiries to some study sponsors to ask about the availability of data from studies they have not listed on this site.

[Find out more »](#)

Review

Research proposals are reviewed by an Independent Review Panel. The study sponsors are not involved in the decisions made by the panel.

[Find out more »](#)

Access

Following approval and after the relevant study sponsor or sponsors receive a signed [Data Sharing Agreement](#), access to the data needed for the research is provided on a password protected website.

[Find out more »](#)

www.clinicalstudydatarequest.com 2014-09-26

How data is made available

How it works

Review of requests

Review of research proposals

Research proposals are checked to make sure the information is complete and that they meet the requirements of this initiative and the sponsor's requirements for informed consent. They are then sent to the [Independent Review Panel](#). The panel considers the following:

- The scientific rationale and relevance of the proposed research to medical science or patient care.
- The ability of the proposed research plan (design, methods and analysis) to meet the scientific objectives. This is a high-level review.
- The publication plan for the research.
- Real or potential conflicts of interest that may impact the planning, conduct or interpretation of the research and proposals to manage these conflicts of interest.
- The qualifications and experience of the research team to conduct the proposed research (a statistician with a degree in statistics or a related discipline should be part of the research team).



www.clinicalstudydatarequest.com 2014-09-26

Scope of Studies to share Patient-Level Data

www.clinicalstudydatarequest.com (status Mar 2014)



Company	Retrospective scope (<u>No</u> industry commitment)	Prospective Scope (= industry commitment)
GSK	Back to Dec 2000 Global interventional studies Phase 1: included	All interventional studies that started in or after 2013 after first approval or termination of development project Phase 1: included
Roche	Back to Jan 1999 Phase 2 - 4 studies Phase 1: per enquiry only if > 50 patients	Phase 2 - 4 studies used as part of regulatory approval or from terminated development projects Phase 1: per enquiry only if > 50 patients
Boehringer	Back to Jan 1998 All studies Phase 1: only multi-center studies	All studies after completion of regulatory review or after termination of development program Phase 1: only multi-center studies
ViiV	Currently unclear (earlier statement „back to 1999“ no longer posted on CSDR.com) Global interventional phase 2 - 4 studies in adults living with HIV Phase 1: unclear	Global interventional phase 2 - 4 studies in adults living with HIV listed on ViiVs trial registry after first approval or termination of development program
Sanofi / Bayer	None, only prospective use	Trials submitted to US and EU regulatory agencies for approved products in EU and US on or after Jan 01 2014
Novartis	None, only prospective use	Studies for newly approved innovative medicines in the US and EU in 2014 [and onwards]



Planned Datasets and Documents to be Shared

Where available, the following anonymized patient level data and information are planned to be provided for clinical studies in scope

- Raw datasets
- Analysis-ready datasets
- Protocol with any amendments
- Annotated case report form
- Statistical analysis plan
- Dataset specifications
- Clinical study report
 - CSR appendices that contain no patient relevant data (e.g. audit certificates or manuals from providers of various diagnostic services) as well as individual patient level data (e.g. narratives) are not included.

Documents will be redacted to protect personal data of study participants, study personnel, and Bayer employees, and to protect Bayer's commercially confidential information, including intellectual property rights.



Data anonymization

New patient identifiers

Center identification removed

Age censored for age 90+ (HIPPA rule)

Dates removed (only relative study time kept)

Verbatim texts removed (only coded information,
e.g. MedDRA kept)

No images, e.g. MRT scans

Case check for rare combinations (e.g. 17-year old male with breast cancer)

See <https://clinicalstudydatarequest.com/Documents/Bayer-Data-Anonymization-Standards-Apr-14-2014.pdf> 2014-09-23



Metrics

ClinicalStudy
DataRequest.com

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Metrics

A summary of the number of research proposals and enquiries that have been submitted since **May 2013** is provided here. Metrics for research proposals are updated monthly and metrics for enquiries are updated every three months.

Research proposals requesting access to patient level data (number of proposals)

Number of Research Proposals submitted up to 30 September 2015		165
Requirements check	In process	10
	Withdrawn by the requestor	18
	Did not meet requirements (further details)	11
	Complete (data available)	72
Research project	In process	72

Transparency works both ways

Details of ongoing and finished research is made public

clinicalstudydatarequest.com
2015-11-04

Recent developments with academia



wellcome^{trust}

Promoting Clinical Trial Data Transparency Conference

When: March 30 & 31, 2015

Where: Harvard Faculty Club, 20 Quincy Street, Cambridge, Massachusetts

Who: Data generators and data users, academic and government agencies, journal leadership, and other stakeholders (by invitation only)

Conference Objectives

- To discuss high-level principles with the explicit goal of developing an approach whereby participant level clinical trial data could be integrated, enabling researchers to access and combine data across the various platforms and sponsors.
- To present and deliberate centrally managed and federated models.
- To discuss implementable solutions to realize harmonization and enable broader data sharing across platforms.

http://mrct.globalhealth.harvard.edu/files/mrct/files/data_sharing_conference_agenda_03-16-2015_final_draft.pdf
accessed 2015-03-23



Opportunities

Increase public trust in clinical trials

Verification of sponsor's pre-planned analysis

Re-analyses within initial objectives and randomization

- Deep drill within study
- Patient level meta-analyses

New research unrelated to initial objectives or randomization



Opportunities: Increase public trust

In medical research

In regulatory action

In drugs' benefit / risk ratio

Opportunities: Verification of sponsor's pre-planned analysis



Already done by FDA statisticians for pivotal phase III trials,
can be viewed in statistical reviews of new drug applications

e.g. http://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/202439Orig1s000StatR.pdf page 16

Per protocol ¹ (out.hypo117)	From randomization up to follow up visit	Follow up visit	283/7004 (4.0%)	252/6958 (3.6%)	0.90 (0.76, 1.07)	0.244
ITT ¹ (out.hypo114)	From randomization up to follow up visit	Follow up visit	285/7090 (4.0%)	257/7081 (3.6%)	0.91 (0.77, 1.08)	0.285
Per protocol ¹ (out.hypo118)	From randomization up to the notification of site date	Site notification	303/7004 (4.3%)	263/6958 (3.8%)	0.87 (0.74, 1.03)	0.101
ITT ¹ (out.hypo115)	From randomization up to the notification of site date	Site notification	306/7090 (4.3%)	269/7081 (3.8%)	0.88 (0.74, 1.03)	0.116
Per protocol ¹ (out.hypo119)	From randomization up to reference end date ^{**}	Reference end date	317/7004 (4.5%)	285/6958 (4.1%)	0.90 (0.77, 1.06)	0.205
ITT ¹ (out.hypo116)	From randomization up to reference end date ^{**}	Reference end date	320/7090 (4.5%)	293/7081 (4.1%)	0.91 (0.78, 1.07)	0.263

(Source (in order of analyses): Clinical Study Report: Study ROCKET-AF;

Table 26 (page 136),

Attachment 6.1 (page 818),

Reviewer's results,

Reviewer's results.

Not always possible due to data anonymization (e.g. age censored at 90)



Opportunities: Deep drill

Analyze study data further (but still within initial objectives and randomization)

- Subgroups
- Different statistical methodology
 - Statistical model
 - Missing data / Questionable data
 - Intention To Treat / modified Intention To Treat / Full Analyses Set
- Endpoints
 - Composite
 - Separate



Opportunities: Deep drill

Original Investigation

Reanalyses of Randomized Clinical Trial Data

Shanil Ebrahim, PhD; Zahra N. Sohani, MSc; Luis Montoya, DDS; Arnav Agarwal, BSc; Kristian Thorlund, PhD; Edward J. Mills, PhD; John P. A. Ioannidis, MD, DSc

IMPORTANCE Reanalyses of randomized clinical trial (RCT) data may help the scientific community assess the validity of reported trial results.

OBJECTIVES To identify published reanalyses of RCT data, to characterize methodological and other differences between the original trial and reanalysis, to evaluate the independence of authors performing the reanalyses, and to assess whether the reanalysis changed interpretations from the original article about the types or numbers of patients who should be treated.

JAMA. 2014;312(10):1024-1032.

Opportunities: Deep drill

Table 2. Differences in Methods Used in the Reanalysis

Differences Cited in the Reanalysis	No. (%)				
	Reanalyses (n = 37) ^a	Did the Reanalysis Modify Inferences of the Original Trial?			
		No (n = 29)	Treat Different Patients (n = 3)	Treat More Patients (n = 13) ^b	Treat Fewer Patients (n = 1)
Differences in statistical or other analytical methods	18 (48.6)	11 (61)	3 (17)	3 (17)	1 (5.5)
Nonparametric statistical technique	1	1			
Separation of composite end points for analysis	1				1
Measure of clinical significance to confirm original findings	2	2			
Informative censoring approach	3	3			
Competing risks model	1		1		
Nonlinear model	2	1	1		
Triangular and restricted sequential design	1	1			

JAMA. 2014;312(10):1024-1032.



Opportunities: Better Meta-Analyses

Currently most meta-analyses are based on publications

With access to patient level data

- Matching patient characteristics at baseline
- Subgroups of your choice (and not what is reported in the papers)

Opportunities: New research

Use the data for new research
unrelated to initial objectives or
randomization

*And now to something
completely different ...*

CAVE! Might not be covered by
historic informed consent



https://en.wikipedia.org/wiki/Monty_Python%27s_Flying_Circus_%28album%29
accessed 2014-01-18



Opportunities: New research

Assessing models for changes in tumour size over time and how they relate to survival times

Raluca Eftimie, PhD, Division of Mathematics, University of Dundee, UK

“There are still many unanswered questions regarding **how**, or even if, **changes in tumour size relate to patient survival**. In addition, to our best knowledge most survival models in the existing literature have never been tested on independent data sets. Such a test is the main purpose of this study. (...)

The research will be conducted **using data from three drugs approved in the metastatic melanoma** setting: Vemurafenib, Trametinib and Dabrafenib. The data from one of these studies will be used to select a tumour growth law model used to develop a survival model. The data from the other two drugs will be used as a validation set.”

Data from 8 studies (6 GSK, 2 Roche) 1,789 patients

At ~60 T€ per patient, this more than 100 million € worth of data

<https://clinicalstudydatarequest.com/Approved-requests-list-946-Roche.aspx> 2014-09-09



Risks

Patient privacy / re-identification

False positive findings

Commercial confidential information

Potential abuse

Risks: Re-Identification of participants

Example of data record

ID	Center	Age	Sex	Height	History	...
1	1	54	M	187	Myopia	...

But from the study report you know also

- The study recruited from December 6th, 2013 to October 14th, 2014.
 - Date of birth is between December 7th, 1958 and October 14th, 1960
- Center 1 is located in Berlin-Wittenau
 - Participant most likely lives or works close by
- The studied illness is mad cow disease
 - Now you can guess ...

Risks: Re-Identification of participants

Real world example

Data known: year of birth, city, major subject at university

The Guardian logo, with "theguardian" in a red, lowercase, sans-serif font.

Search


Teenager finds sperm donor dad on internet

Ian Sample, science correspondent
The Guardian, Thursday 3 November 2005

Using nothing more than a swab of saliva and the internet, a 15-year-old boy has tracked down his anonymous sperm donor father, according to details released today.

<http://www.theguardian.com/science/2005/nov/03/genetics.news/print> 2014-09-17

Risks: Re-Identification of participants

A white box for the 23andMe DNA kit. It features a colorful, abstract geometric design on the left side. The text "welcome to you®" is printed in a large, grey, sans-serif font. Below it, the 23andMe logo is visible, consisting of a stylized 'X' made of two overlapping lines (one green, one pink) and the text "23andMe".

welcome to you®

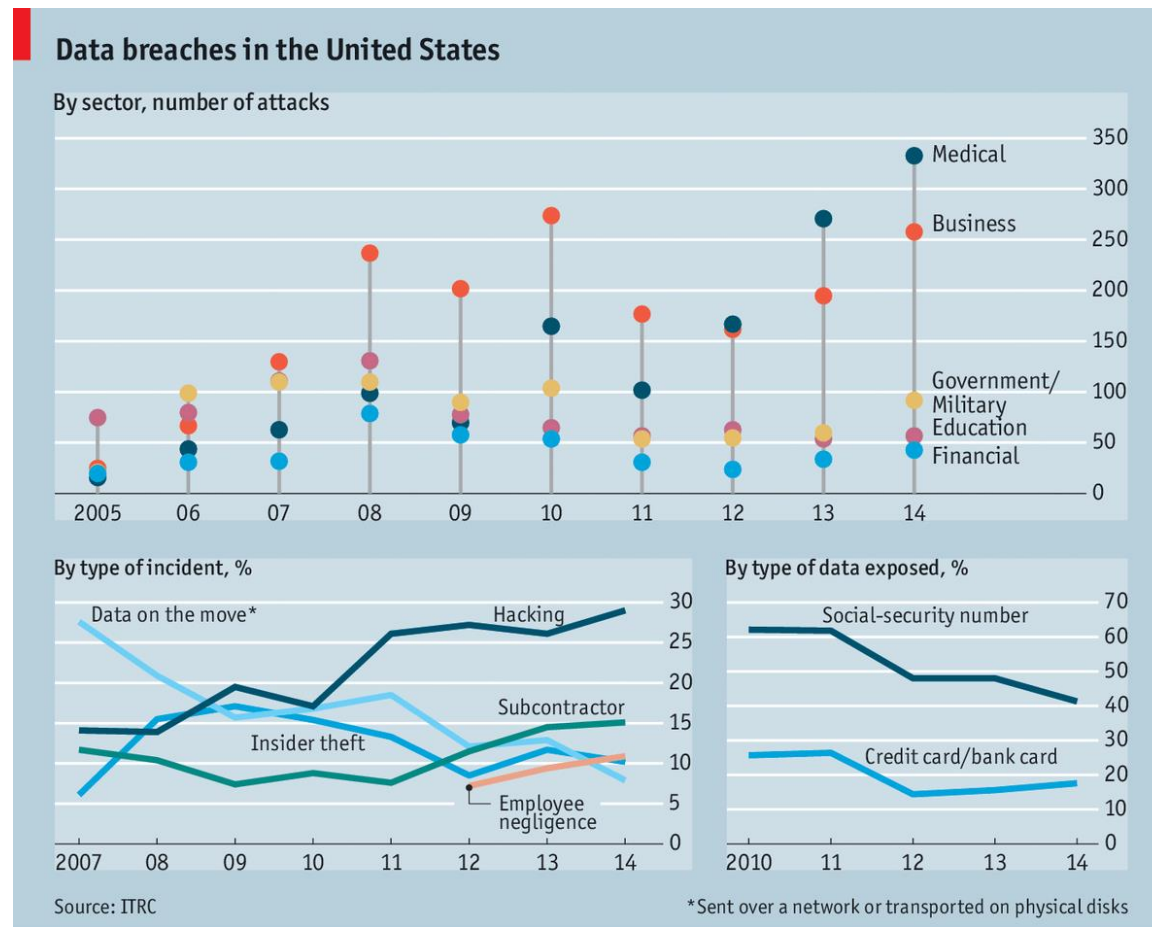
Find out what your DNA says about you and your family.

- Learn what percent of your DNA is from populations around the world
- Contact your DNA relatives across continents or across the street
- Build your family tree and enhance your experience with relatives

order now **\$99**

23andme.com 2014-09-17

Risks: Data breaches



Economist.com

http://cdn.static-economist.com/sites/default/files/imagecache/original-size/images/print-edition/20151107_WBC503_1.png 2015-11-15

Risks: False positive findings

“pill scare” due to false positive finding

Have to account for multiplicity

A true positive finding is an opportunity -
not a risk (!)

ZEIT ONLINE | GESUNDHEIT

RISKANTER GERINNUNGSHEMMER

256 Menschen weltweit sterben nach der Behandlung mit Pradaxa

Ein neuer Blutverdünner forderte fünfmal mehr Todesopfer als von Hersteller Boehringer zunächst angegeben. Das hat das Pharmaunternehmen jetzt bestätigt.

von Jutta Hoffritz | 12. November 2011 - 08:17 Uhr



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 November 2011
EMA/CHMP/903767/2011
Press Office

[Press release](#)

[European Medicines Agency updates on safety of Pradaxa](#)

<http://pdf.zeit.de/wissen/gesundheit/2011-11/blutverduenner-boehringer.pdf> 2012-12-31
http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2011/11/WC500117818.pdf 2014-09-29

Risks: release of commercial confidential information



Not a statistical topic

Commercial confidential information unrelated to public health

- Which centers recruit many patients with only a few protocol deviations?
- Which suppliers were used

Usage of study reports and/or data to register a generic drug in third countries while the intellectual property is still protected in EU

Publication of results while a patent application is pending

Risks: Potential abuse

Submit a sound analysis plan and get access

Do something else



en.wikipedia.org/wiki/Four_in_a_Jeep 2014-09-26



Side effects

Data transparency is not for free

- Department at Bayer “Clinical Trial Transparency”
- Work to be done at
 - Statistics & Data Management
 - Medical Writing
 - Drug Discovery / Clinical Development / Medical Affairs
- External costs for
 - ClinicalStudyDataRequest.com website
 - Review Panel
 - Protected data storage on external server
 - Software licenses (e.g. SAS)

Other data sharing initiatives

German statutory health insurance data

www.dimdi.de/static/de/versorgungsdaten/index.htm
2014-03-03



DIMDI
medizinwissen
Deutsches Institut für Medizinische Dokumentation und Information

English Presse | Kontakt Suche

Ihre Position: Startseite » Versorgungsdaten

Informationssystem Versorgungsdaten (Datentransparenz)

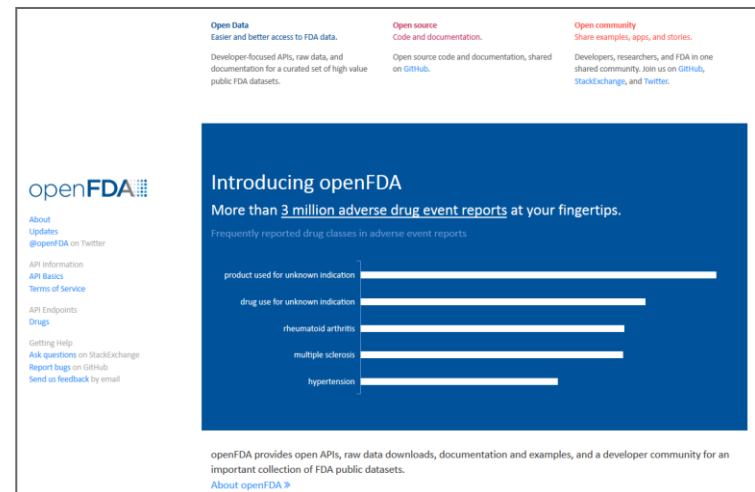
Das Informationssystem Versorgungsdaten (Datentransparenz) nimmt in der Kalenderwoche 8 (17. - 21.02.2014) den Pilotbetrieb auf. Nutzungsberechtigte können dann bei uns die Bereitstellung aggregierter Versorgungsdaten der gesetzlichen Krankenkassen beantragen. Diese können insbesondere für Analysen des Versorgungsgeschehens im Rahmen der Versorgungsforschung und für Steuerungsaufgaben in der gesetzlichen Krankenversicherung genutzt werden. Die DaTraV-Daten beinhalten u.a. Angaben über ambulante und stationäre Behandlungen sowie zur ambulanten Arzneimittelversorgung der gesetzlich Versicherten.

Der Pilotbetrieb ermöglicht es, Daten im Rahmen der Datenfernverarbeitung unter Verwendung von SQL (Oracle 11g R2) zu analysieren. Dabei werden die DaTraV-Daten mit von den Nutzungsberechtigten bereitgestellten Programmen ausgewertet, die wir vorab geprüft und genehmigt haben.

Eine erste Ausbaustufe realisieren wir im 2. Quartal 2014. Dann werden wir ergänzend anbieten, die DaTraV-Daten entsprechend einer vom Antragsteller formulierten Fragestellung auszuwerten. D.h. wir entwickeln in diesem Fall die erforderlichen Programme.

FDA open data initiative (spontaneous ADRs)

open.fda.gov 2014-06-20



Open Data
Easier and better access to FDA data.
Developer-focused APIs, raw data, and documentation for a curated set of high value public FDA datasets.

Open source
Code and documentation.
Open source code and documentation, shared on GitHub.

Open community
Share examples, apps, and stories.
Developers, researchers, and FDA in one shared community. Join us on GitHub, StackExchange, and Twitter.

Introducing openFDA

More than **3 million adverse drug event reports** at your fingertips.

Frequently reported drug classes in adverse event reports

Drug Class	Frequency (Relative)
product used for unknown indication	High
drug use for unknown indication	Medium-High
rheumatoid arthritis	Medium
multiple sclerosis	Medium-Low
hypertension	Low

openFDA provides open APIs, raw data downloads, documentation and examples, and a developer community for an important collection of FDA public datasets.
[About openFDA](#)

EFSPI working group on data sharing

Objectives:

- To identify and prospectively prioritize statistical issues in data transparency
- To co-ordinate statistical contributions across Europe to the data transparency debate
- To disseminate relevant information on the topic across the statistical community
- To develop and share a vision of the potential longer term impact of data transparency.



- More on www.efspi.org



Conclusion

Clinical trial data is becoming rapidly more transparent

In my view, the opportunities do outweigh the inherent risks

We still need

- Good secondary data analysis practice
- Commitment from other sponsors than industry



Recommended Reading

Eichler H-G, Abadie E, Breckenridge A, Leufkens H, Rasi G.
Open Clinical Trial Data for All? A View from Regulators.
PLoS Med 9(4) 2012: e1001202. doi:10.1371/journal.pmed.1001202

Fletcher C, Driessen S, Burger HU, Gerlinger C, Biesheuvel E; EFSPI.
European Federation of Statisticians in the Pharmaceutical Industry's position
on access to clinical trial data.
Pharm Stat. 2013;12(6):333-6.

ClinicalStudyDataRequest.com 2015-11-04

EMA policy # 70

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/10/WC500174796.pdf 2014-10-07

EMA draft policy # 70 www.ema.europa.eu/docs/en_GB/document_library/Other/2013/06/WC500144730.pdf 2014-04-28