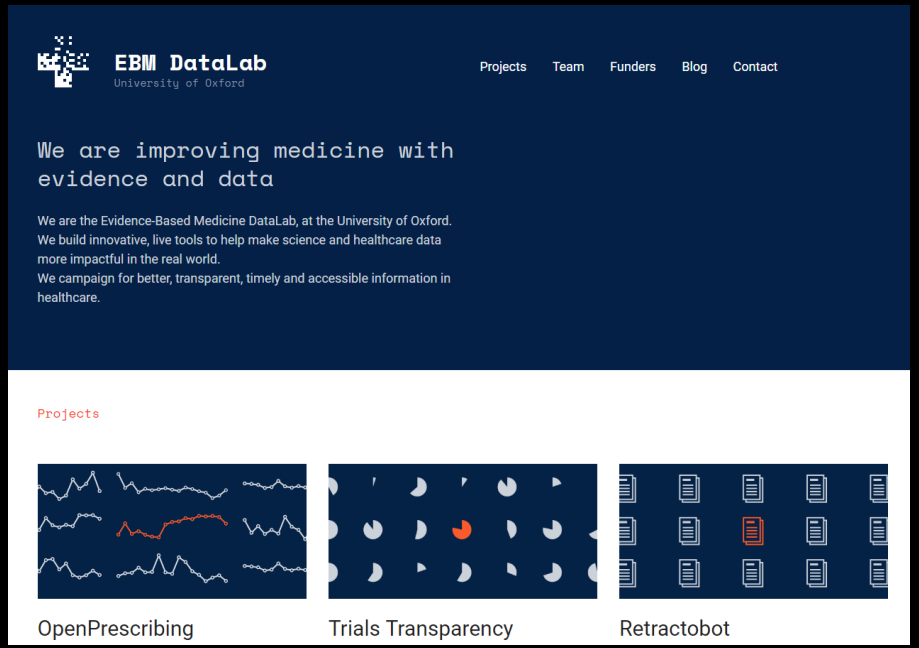
The TrialsTracker Project

Live Audit and Feedback for Trials Transparency

Nicholas DeVito
DPhil Candidate - DataLab

The DataLab


EBM DataLab
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We are improving medicine with evidence and data
We are the Evidence-Based Medicine DataLab, at the University of Oxford.
We build innovative, live tools to help make science and healthcare data more impactful in the real world.
We campaign for better, transparent, timely and accessible information in healthcare.
Projects
OpenPrescribing
Trials Transparency
Retractobot

NHS Airedale, Wharfedale and Craven CCG

There are 18 practices currently in this CCG. » show them...

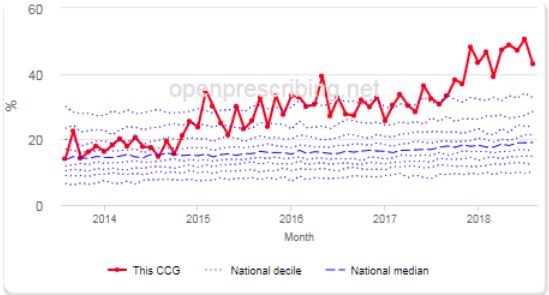
Standard measures

Our 59 standard measures compare performance across England. This is the measure where NHS Airedale, Wharfedale and Craven CCG has the greatest potential for improvement. View all 59 measures...

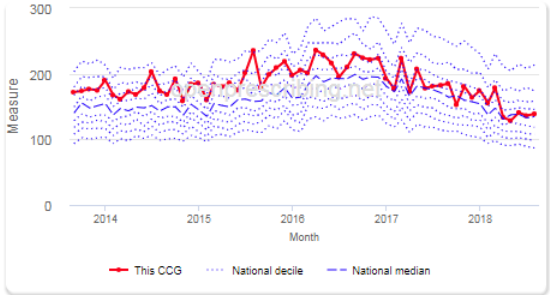
NHS low priority measures

These are measures about low-value items which NHS England says should not routinely prescribed in primary care. This is the ranking of NHS Airedale, Wharfedale and Craven CCG for all low-value items combined. View the 17 measures...

Nebivolol 2.5mg tablets



NHS England Low Priority Treatment - All Low Priority Treatments



Research Integrity

Trials Transparency

House of Commons

Science and Technology Committee

Research integrity: clinical trials transparency

Tenth Report of Session 2017–19

Report, together with formal minutes relating to the report

Ordered by the House of Commons to be printed 23 October 2018

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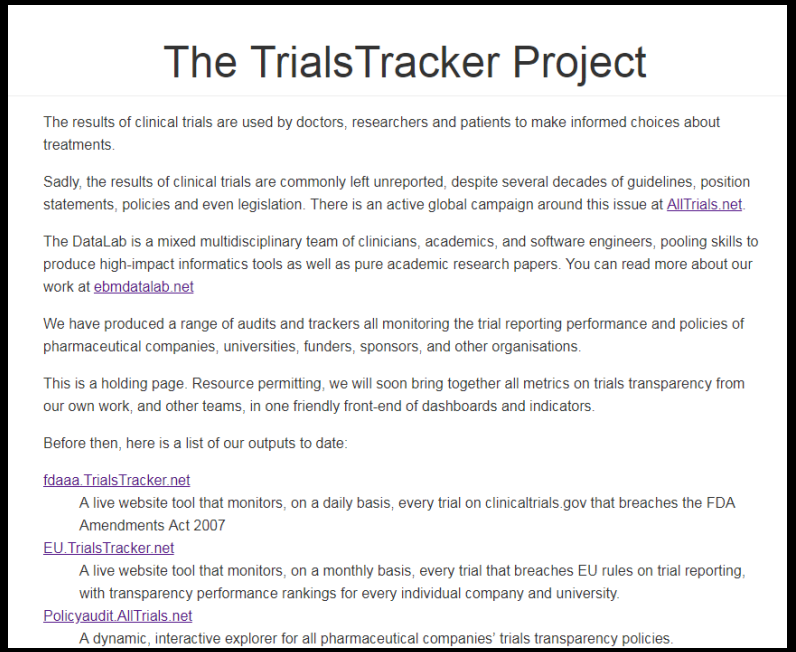
The TrialsTracker Project



The TrialsTracker Project

The results of clinical trials are used by doctors, researchers and patients to make informed choices about treatments.

Sadly, the results of clinical trials are commonly left unreported, despite several decades of guidelines, position statements, policies and even legislation. There is an active global campaign around this issue at AllTrials.net.

The DataLab is a mixed multidisciplinary team of clinicians, academics, and software engineers, pooling skills to produce high-impact informatics tools as well as pure academic research papers. You can read more about our work at ebmdatalab.net

We have produced a range of audits and trackers all monitoring the trial reporting performance and policies of pharmaceutical companies, universities, funders, sponsors, and other organisations.

This is a holding page. Resource permitting, we will soon bring together all metrics on trials transparency from our own work, and other teams, in one friendly front-end of dashboards and indicators.

Before then, here is a list of our outputs to date:

fdaaa.TrialsTracker.net
: A live website tool that monitors, on a daily basis, every trial on clinicaltrials.gov that breaches the FDA Amendments Act 2007

EU.TrialsTracker.net
: A live website tool that monitors, on a monthly basis, every trial that breaches EU rules on trial reporting, with transparency performance rankings for every individual company and university.

Policyaudit.AllTrials.net
: A dynamic, interactive explorer for all pharmaceutical companies' trials transparency policies.

www.trialstracker.net

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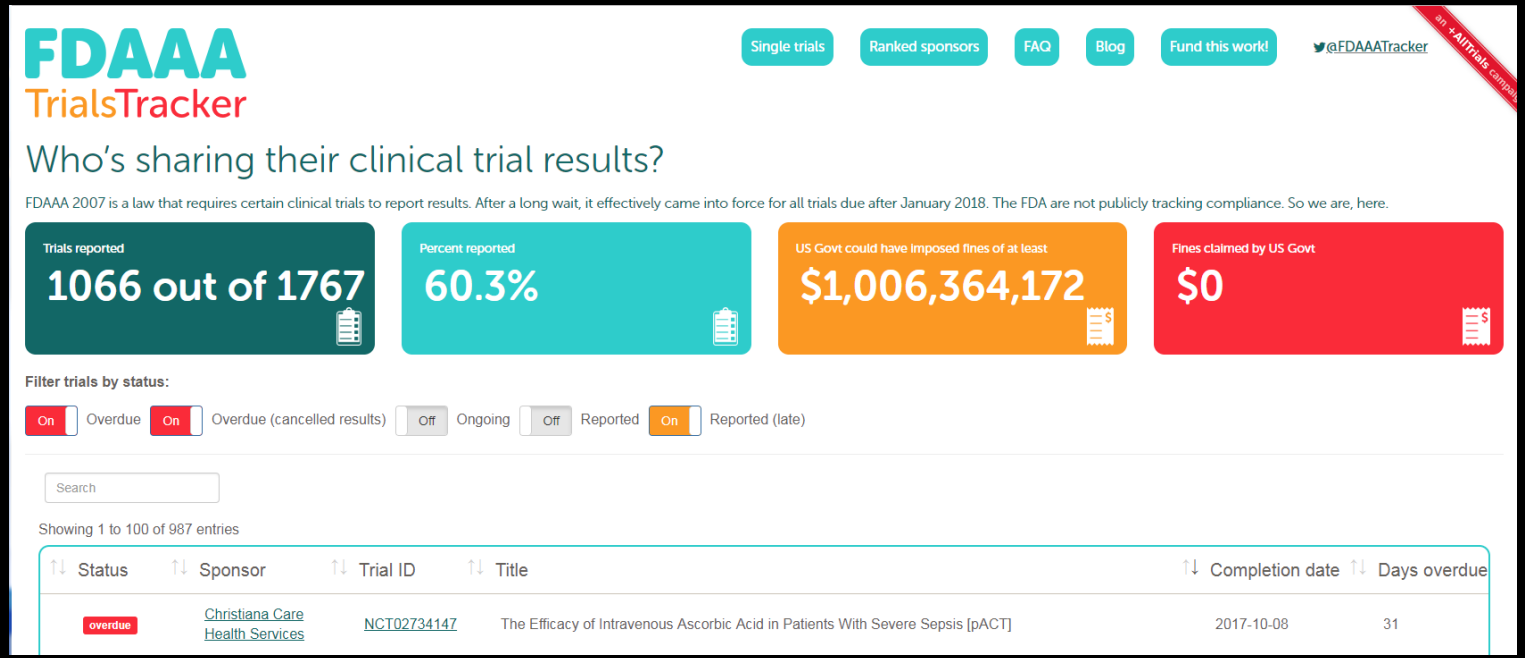
FDAAA TrialsTracker



DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 11

[Docket Number NIH–2011–0003]

RIN 0925–AA55

Clinical Trials Registration and Results Information Submission

AGENCY: National Institutes of Health, Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: This final rule details the requirements for submitting registration and summary results information, including adverse event information, for specified clinical trials of drug products (including biological products) and device products and for pediatric postmarket surveillances of a device product to *ClinicalTrials.gov*, the clinical trial registry and results data bank operated by the National Library of Medicine (NLM) of the National Institutes of Health (NIH). This rule provides for the expanded registry and results data bank specified in Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) to help patients find trials for which they might be eligible, enhance the design of clinical trials and prevent duplication of unsuccessful or unsafe trials, improve the evidence base that informs clinical care, increase the efficiency of drug and device development processes, improve clinical research practice, and build public trust in clinical research. The requirements apply to the responsible party (including the sponsor or designated principal investigator) for certain clinical trials of drug products (including biological products) and device products that are regulated by the Food and Drug Administration (FDA) and for pediatric postmarket surveillances of a device product that are ordered by FDA.

DATES: These regulations are effective on January 18, 2017. Additional information on the effective date and the compliance date can be found in Section IV.F.

FOR FURTHER INFORMATION CONTACT:

Regulatory Process: Jerry Moore, NIH Regulations Officer, Office of Management Assessment, telephone (301–496–4607) (not a toll-free number), Fax (301–402–0169), or by email at *jm4tz@nih.gov*.

Technical Information: Kevin Fain, Senior Advisor for Policy and Research, *ClinicalTrials.gov*, National Center for Biotechnology Information, NLM, NIH, Department of Health and Human Services, telephone (301–402–0650) (not a toll-free number), Fax 301–402–0118, or by email at *register@clinicaltrials.gov*.

SUPPLEMENTARY INFORMATION:

Executive Summary

Purpose of This Regulatory Action

This final rule clarifies and expands requirements for the submission of clinical trial registration and results information to the *ClinicalTrials.gov* database, which is operated by the NLM. It implements the provisions of section 402(j) of the Public Health Service Act (PHS Act) (42 United States Code (U.S.C.) 282(j)) as amended by Title VIII of FDAAA and including technical corrections made to FDAAA under Public Law 110–316), which were intended to improve public access to information about certain clinical trials of U.S. FDA-regulated drugs, biological products, and devices (also referred to as ''FDA-regulated drugs, biological products, and devices'' in this preamble) and certain pediatric postmarket surveillances of a device. Under section 402(j) of the PHS Act, those responsible for specified clinical trials of these FDA-regulated products have been required to submit registration information to *ClinicalTrials.gov* since December 26, 2007, summary results information for clinical trials of approved products as of September 27, 2008, and certain adverse events information since September 27, 2009. Section 402(j) of the PHS Act requires the Secretary of Health and Human Services to use rulemaking to expand the requirements for submission of summary results information, and authorizes the Secretary to use rulemaking to make other changes that enhance, but do not decrease, the available information about the specified trials.

This final rule does not impose requirements on the design or conduct of clinical trials or on the data that must be collected during clinical trials. Instead it specifies how data that were collected and analyzed in accordance with a clinical trial's protocol are submitted to *ClinicalTrials.gov*. No patient-specific data are required to be submitted by this rule or by the law this rule is intended to implement.

The major provisions of this rule are summarized below. More detailed discussions of these provisions are in Sections III and IV of this preamble.

Summary of the Major Provisions of the Regulatory Action

Applicable Clinical Trial

This final rule clarifies which clinical trials of FDA-regulated drug products (including biological products) and device products and which pediatric postmarket surveillances of a device product, are applicable clinical trials for which information must be submitted to *ClinicalTrials.gov*. The final rule considers all interventional clinical trials with one or more arms and with one or more pre-specified outcome measures to be controlled clinical trials. The final rule does not consider any expanded access use (*e.g.*, access under treatment INDs or treatment protocols, which provide widespread access, access for extremely small patient populations, or access for individual patients) to be an applicable clinical trial. The final rule also describes an approach for evaluating, prior to registration, whether a particular clinical trial or study is an applicable clinical trial (see Section IV.A.5 and Section IV.B.2).

Responsible Party

This final rule specifies that there must be one (and only one) responsible party for purposes of submitting information about an applicable clinical trial. The sponsor of an applicable clinical trial will be considered the responsible party, unless and until the sponsor designates a qualified principal investigator as the responsible party. This final rule specifies the approach for determining who will be considered the sponsor of an applicable clinical trial under various conditions, what qualifies a principal investigator to be designated a responsible party by a sponsor, and how responsibility reverts to the sponsor if a designated principal investigator is unable to fulfill the requirements for submitting information to *ClinicalTrials.gov* unless and until the sponsor designates another principal investigator as the responsible party (see Section IV.A.2).

Registration

This final rule specifies requirements for registering applicable clinical trials at *ClinicalTrials.gov*. It requires that the responsible party register an applicable clinical trial not later than 21 calendar days after enrolling the first human subject (also referred to as participant or subject), and it specifies the data elements of clinical trial information that must be submitted at the time of registration. These data elements include the descriptive information, recruitment information, location and contact information, and administrative data elements listed in section 402(j) of the PHS Act, as well as additional required data elements under the Secretary's authority to modify the registration information requirements by

rulemaking as long as such modifications improve, and do not reduce, the clinical trial information available to the public in *ClinicalTrials.gov*. We consider these additional required registration data elements necessary to enable the NIH to implement other statutory provisions, indicate the status of human subjects protection review of the trial, facilitate the public's ability to search and retrieve information from *ClinicalTrials.gov*, and help ensure that entries are meaningful and unambiguous. We find that some of these additional data elements required under this rule were included in *ClinicalTrials.gov* before FDAAA was enacted or have been implemented since 2007 as optional data elements (see Section IV.B).

Although section 402(j) of the PHS Act includes a provision delaying public posting of registration information for applicable clinical trials of unapproved or uncleared device products until the device product is approved or cleared, the final rule includes a provision under which the responsible party for an applicable device clinical trial can indicate to the Agency that it is authorizing the public posting of clinical trial registration information that would otherwise fall under the delayed posting provision prior to approval or clearance of the product (see Section IV.B.5).

Expanded Access Information

Section 402(j) of the PHS Act requires the submission of information regarding whether, for an applicable drug clinical trial of an unapproved drug product (including an unlicensed biological product), expanded access to the investigational product being studied in the applicable clinical trial is available under section 561 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). If the responsible party for an applicable clinical trial of an unapproved drug product (including an unlicensed biological product) is both the sponsor of the applicable clinical trial being registered and the manufacturer of the unapproved product, this rule requires the submission of a separate expanded access record containing details about how to obtain access to the investigational product. Once an expanded access record has been created for a particular investigational product and a National Clinical Trial (NCT) number has been assigned to it, the responsible party must update the applicable clinical trial(s) with that NCT number and provide that NCT number when submitting clinical trial registration information for any future applicable clinical trial(s) studying the same investigational product. The NCT number for the expanded access record allows *ClinicalTrials.gov* to link the existing expanded access record to the study record for the clinical trial (see Section IV.B.5 and Section IV.D.3).

Results Information Submission

This final rule addresses the statutory requirement for the submission of summary results information for applicable clinical trials of drug products (including biological products) and device products that are approved, licensed, or cleared by FDA. It also extends the requirement for results information submission to applicable clinical trials of drug products (including biological products) and device products that are not approved, licensed, or cleared by FDA. The rule requires the submission of data in a tabular format summarizing participant flow; demographic and baseline characteristics; primary and secondary outcomes, as well as results of any scientifically appropriate statistical tests; and adverse event information. In addition, the rule requires the submission of the full protocol and statistical analysis plan (if a separate document) (see Section III.D).

In general, this rule requires the submission of results information not later than 1 year after the completion date (referred to as the ''primary completion date'') of the clinical trial, which is defined as the date of final data collection for the primary outcome measure. Results information submission could be delayed for up to 2 additional years from the date of submission of a certification that either an unapproved, unlicensed, or uncleared product studied in the trial is still under development by the manufacturer or that approval will be sought within 1 year after the primary completion date of the trial for a new use of an approved, licensed, or cleared product that is being studied in the trial. This rule also permits responsible parties to request extensions to the results information submission deadlines for ''good cause'' as well as a permanent waiver of results information submission requirements for extraordinary circumstances (see Section IV.C.3 and Section IV.C.6).

Adverse Events Information

This final rule requires the responsible party to submit information summarizing the number and frequency of adverse events experienced by participants enrolled in a clinical trial, by arm or comparison group, as well as a brief description of each arm or group as a component of clinical trial results information. It also requires submission of three tables of adverse event information: One summarizing all serious adverse events; another one summarizing other adverse events that occurred with a frequency of 5 percent or more in any arm of the clinical trial; and finally, one summarizing all-cause mortality data by arm or group. This final rule clarifies that these adverse event tables must include information about events that occurred, regardless of whether or not they were anticipated or unanticipated. In addition, this rule requires responsible parties to provide the time frame for adverse event data collection and specify whether the collection approach for adverse events was systematic or non-systematic. The final rule does not require a responsible party to collect adverse event information that is not specified in the protocol (see Section IV.C.4).

Updates and Other Required Information

This final rule requires that all submitted information be updated at least annually if there are changes to report. More rapid updating is required for several data elements to help ensure that users of *ClinicalTrials.gov* have access to accurate, up-to-date information about important aspects of an applicable clinical trial or other clinical trial. The final rule also requires timely corrections to any errors discovered by the responsible party or the Agency during quality control review of submissions or after the information has been posted. The rule clarifies that the responsible party's obligation to submit updates and correction of errors ends on the date on which the required data elements for clinical trial results information have been submitted for all primary and secondary outcomes and all adverse events that were collected in accordance with the protocol, and the quality control review process has concluded (see Section IV.D.3).

Effective Date and Compliance Date

This final rule will be effective January 18, 2017. As of that date, the *ClinicalTrials.gov* system will allow responsible parties to comply with the rule. Responsible parties will have 90 calendar days after the effective date to come into compliance with the requirements of this rule (see Section IV.F).

Legal Consequences of Non-Compliance

This final rule outlines the potential civil or criminal actions, civil monetary penalty actions, and grant funding

actions that may be taken if responsible parties fail to comply with the rule's requirements. It does not outline all potential legal consequences, *e.g.*, laws governing the veracity of information submitted to the federal government, however, and should not be understood as describing the exclusive means of enforcement that the government might undertake with respect to compliance with the provisions of section 402(j) of the PHS Act, including these regulations (see Section IV. E).

Costs and Benefits

Based on our cost estimates, this regulatory action is expected to result in $59.6 million in annual costs, and it is not expected to have a significant impact on the economy. The costs consist primarily of the time needed to organize, format, and submit to *ClinicalTrials.gov* information that was prepared for or collected during the clinical trial (*e.g.*, summary of key protocol details and clinical trial results information). The potential benefits include greater public access to information about ongoing and completed applicable clinical trials. Such information may help potential clinical trial participants to better understand their options for participating in new trials; to better enable funders and clinical researchers to determine the need for new trials; to provide more complete information for those who use evidence from clinical trials to inform medical and other decisions; and to better enable the scientific community to examine the overall state of clinical research as a basis for engaging in quality improvement (*e.g.*, with regard to research methods). The rule is also expected to provide greater clarity about what is required for those who are subject to the legal mandate to submit information to *ClinicalTrials.gov* (see Section V).

Commonly Used Abbreviations

ANDA Abbreviated New Drug Application
API Application Program Interface
BLA Biologics License Application
CBER Center for Biologics Evaluation and Research, FDA
CDER Center for Drug Evaluation and Research, FDA
CDISC Clinical Data Interchange Standards Consortium
CDRH Center for Devices and Radiological Health, FDA
CFR Code of Federal Regulations
CONSORT Consolidated Standards of Reporting Trials
CSR Clinical Study Report
CTRP Clinical Trial Reporting Program, NCI
EMA European Medicines Agency
EU European Union
EudraCT European Clinical Trials Database
FDA Food and Drug Administration, HHS
FDAAA Food and Drug Administration Amendments Act of 2007
FDAMA Food and Drug Administration Modernization Act of 1997
FD&C Act Federal Food, Drug, and Cosmetic Act
FOIA Freedom of Information Act
FR Federal Register
HDE Humanitarian Device Exemption
HHS Department of Health and Human Services
ICH International Conference on Harmonization of Technical Requirements of Pharmaceuticals for Human Use
ICMJE International Committee of Medical Journal Editors
IDE Investigational Device Exemption
IND Investigational New Drug Application
IOM Institute of Medicine (now the Health and Medicine Division of the National Academies of Sciences, Engineering, and Medicine)
IPD Individual Participant Data
IRB Institutional Review Board
IVD In Vitro Diagnostic
LPLV Last Patient Last Visit
MedDRA Medical Dictionary for Regulatory Affairs
MeSH® Medical Subject Headings
NCI National Cancer Institute, NIH
NCT National Clinical Trial
NDA New Drug Application
NIH National Institutes of Health, HHS
NLM National Library of Medicine, NIH
NPRM Notice of Proposed Rulemaking
OHRP Office for Human Research Protections, HHS
PCORI Patient-Centered Outcomes Research Institute
PDF Portable Document Format
PHS Act Public Health Service Act
PMA Premarket Approval
PRS Protocol Registration and Results System, *ClinicalTrials.gov*
RFA Regulatory Flexibility Act
SAP Statistical Analysis Plan
SNOMED CT® Systematized Nomenclature of Medicine—Clinical Terms®
UMLS Unified Medical Language System
U.S. United States
U.S.C. United States Code
U.S. TSA U.S. Trade Secrets Act
UTSA Uniform Trade Secrets Act, Uniform Law Commission
WHO World Health Organization
XML Extensible Markup Language

Table of Contents

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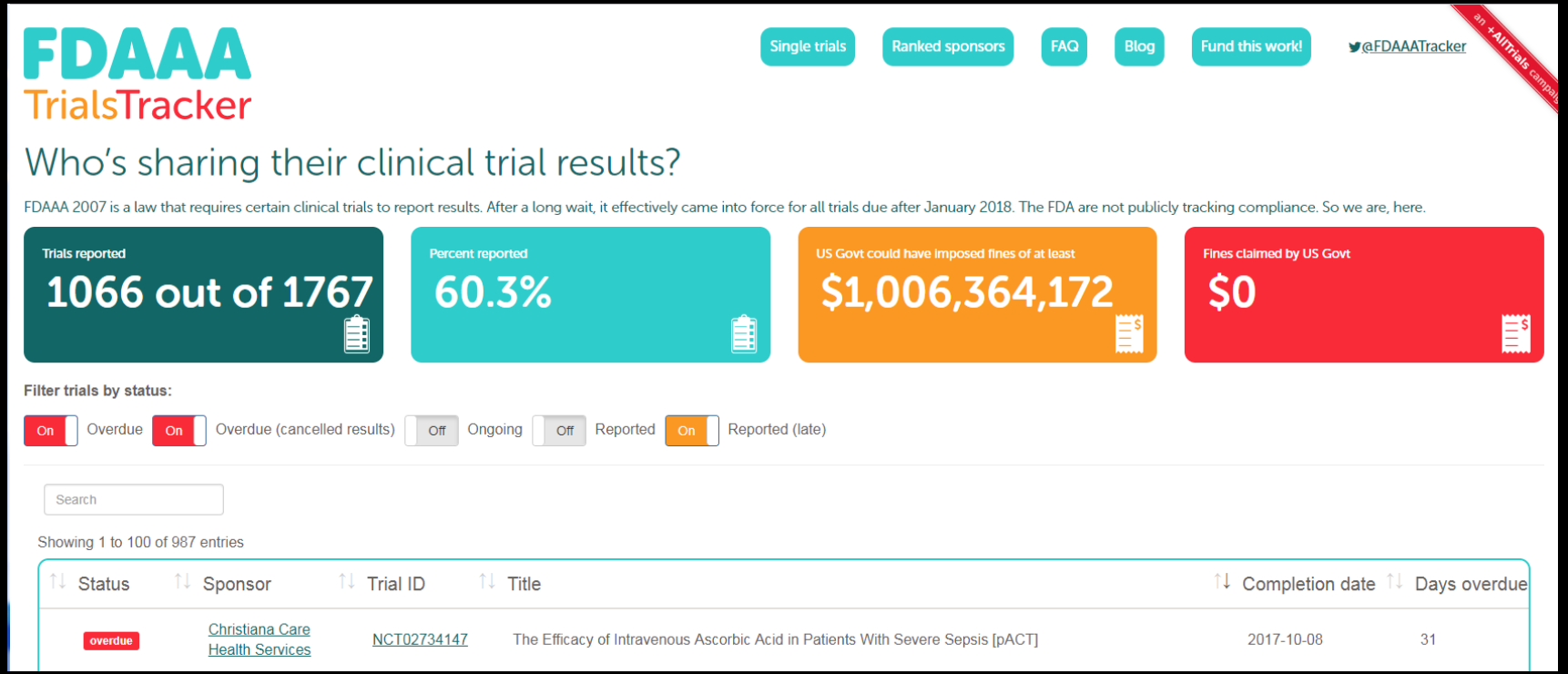
FDAAA
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Who's sharing their clinical trial results?
FDAAA 2007 is a law that requires certain clinical trials to report results. After a long wait, it effectively came into force for all trials due after January 2018. The FDA are not publicly tracking compliance. So we are, here.
Trials reported
1066 out of 1767
Percent reported
60.3%
US Govt could have imposed fines of at least
$1,006,364,172
Fines claimed by US Govt
$0
Filter trials by status:
On Overdue
On Overdue (cancelled results)
Off Ongoing
Off Reported
On Reported (late)
Search
Showing 1 to 100 of 987 entries
Status
Sponsor
Trial ID
Title
Completion date
Days overdue
overdue
Christiana Care Health Services
NCT02734147
The Efficacy of Intravenous Ascorbic Acid in Patients With Severe Sepsis [pACT]
2017-10-08
31

Policy Assessment

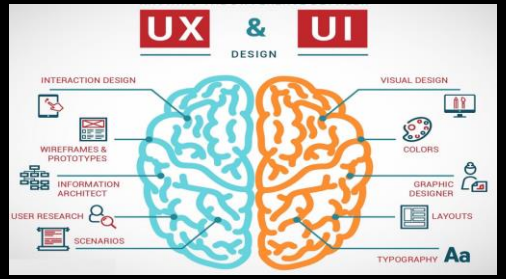
Development

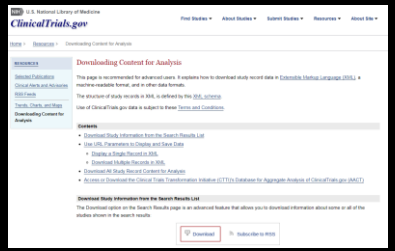
Google BigQuery

GitHub

python™

How to Present?





Technical Assessment

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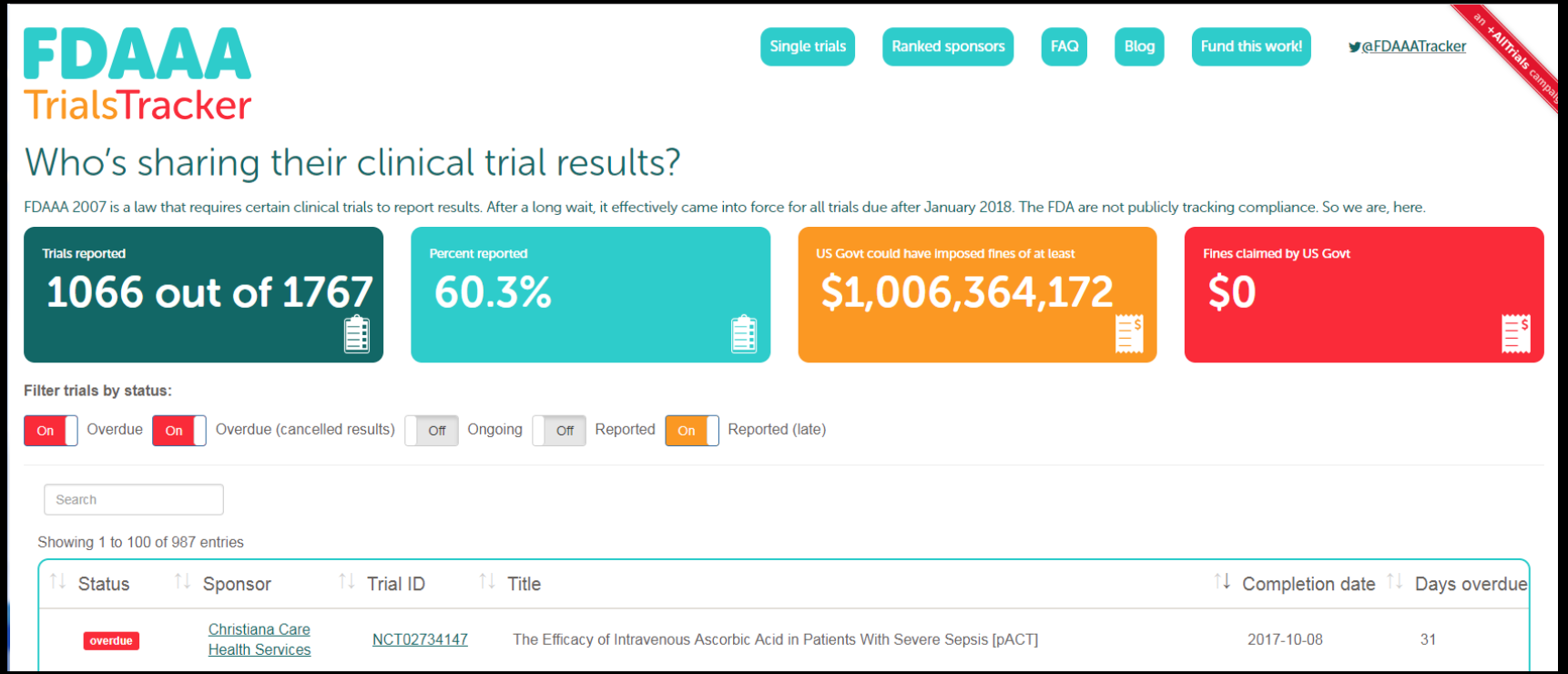
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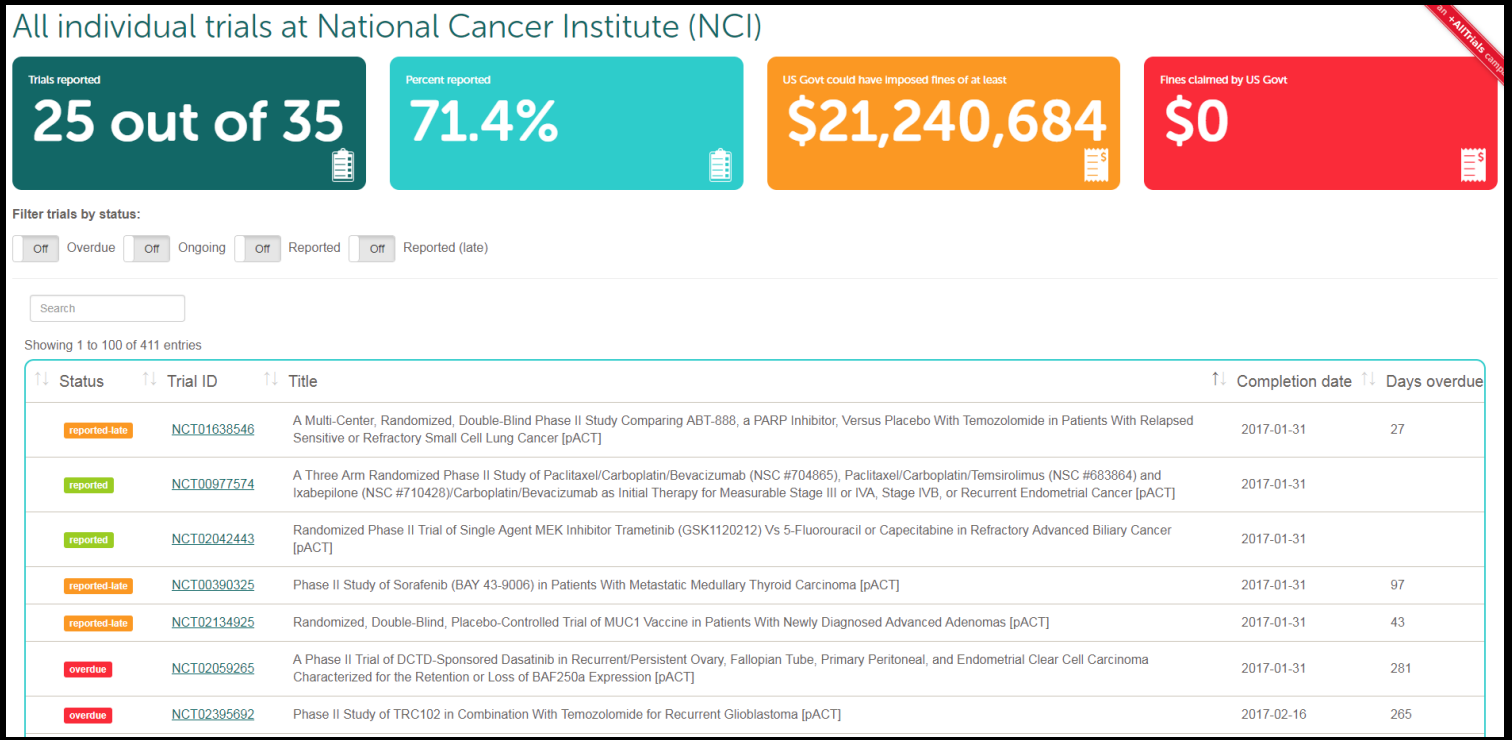
Status
Sponsor
Trial ID
Title
Completion date
Days overdue
overdue
Christiana Care Health Services
NCT02734147
The Efficacy of Intravenous Ascorbic Acid in Patients With Severe Sepsis [pACT]
2017-10-08
31

Sponsor name	Due	Reported	Percent
M.D. Anderson Cancer Center	45	32	71%
National Cancer Institute (NCI)	35	25	71%
Massachusetts General Hospital	26	25	96%
GlaxoSmithKline	25	25	100%
Pfizer	22	22	100%
Novartis Pharmaceuticals	22	21	95%
Memorial Sloan Kettering Cancer Center	21	21	100%
Gilead Sciences	20	20	100%
AstraZeneca	19	19	100%
University of California, San Francisco	18	5	27%
Johns Hopkins University	15	15	100%
Emory University	15	15	100%
The University of Texas Health Science Center, Houston	15	15	100%
Mayo Clinic	15	4	26%
Hoffmann-La Roche	14	13	92%
Eli Lilly and Company	13	13	100%

All individual trials at National Cancer Institute (NCI)



Status	Trial ID	Title	Completion date	Days overdue
reported-late	NCT01638546	A Multi-Center, Randomized, Double-Blind Phase II Study Comparing ABT-888, a PARP Inhibitor, Versus Placebo With Temozolomide in Patients With Relapsed Sensitive or Refractory Small Cell Lung Cancer [pACT]	2017-01-31	27
reported	NCT00977574	A Three Arm Randomized Phase II Study of Paclitaxel/Carboplatin/Bevacizumab (NSC #704865), Paclitaxel/Carboplatin/Temsirolimus (NSC #683864) and Ixabepilone (NSC #710428)/Carboplatin/Bevacizumab as Initial Therapy for Measurable Stage III or IVA, Stage IVB, or Recurrent Endometrial Cancer [pACT]	2017-01-31	
reported	NCT02042443	Randomized Phase II Trial of Single Agent MEK Inhibitor Trametinib (GSK1120212) Vs 5-Fluorouracil or Capecitabine in Refractory Advanced Biliary Cancer [pACT]	2017-01-31	
reported-late	NCT00390325	Phase II Study of Sorafenib (BAY 43-9006) in Patients With Metastatic Medullary Thyroid Carcinoma [pACT]	2017-01-31	97
reported-late	NCT02134925	Randomized, Double-Blind, Placebo-Controlled Trial of MUC1 Vaccine in Patients With Newly Diagnosed Advanced Adenomas [pACT]	2017-01-31	43
overdue	NCT02059265	A Phase II Trial of DCTD-Sponsored Dasatinib in Recurrent/Persistent Ovary, Fallopian Tube, Primary Peritoneal, and Endometrial Clear Cell Carcinoma Characterized for the Retention or Loss of BAF250a Expression [pACT]	2017-01-31	281
overdue	NCT02395692	Phase II Study of TRC102 in Combination With Temozolomide for Recurrent Glioblastoma [pACT]	2017-02-16	265

NCT02658851: An overdue trial by Bovie Medical Corporation

This trial is overdue. It was due to report 4 months, 2 weeks ago.

Think we've made a mistake? Before contacting us, review the criteria in our paper. In particular, bear in mind the following:

- We can only rely on the structured data that sponsors put into the registry: they may enter incorrect or incomplete data.
- Reporting in a journal is not enough. The FDAAA rules state that the trial must be reported on ClinicalTrials.gov.
- Terminated trials are required to report results. Only withdrawn trials (which never recruited a single patient) are not.

Full data

Full entry on ClinicalTrials.gov	NCT02658851
Title	**Application of Cold Plasma Energy for Reduction of Lymphoceles Following Pelvic Lymph Node Dissection During Robot-Assisted Radical Prostatectomy**
Results Status	Overdue
ACT or pACT?	This is what FDAAA officially calls a "probable Applicable Clinical Trial"
Start date	June 30, 2016
Completion date	June 27, 2017
Required reporting date	June 27, 2018, midnight
Actual reporting date	None
Date last checked at ClinicalTrials.gov	Nov. 8, 2018
Days late	134

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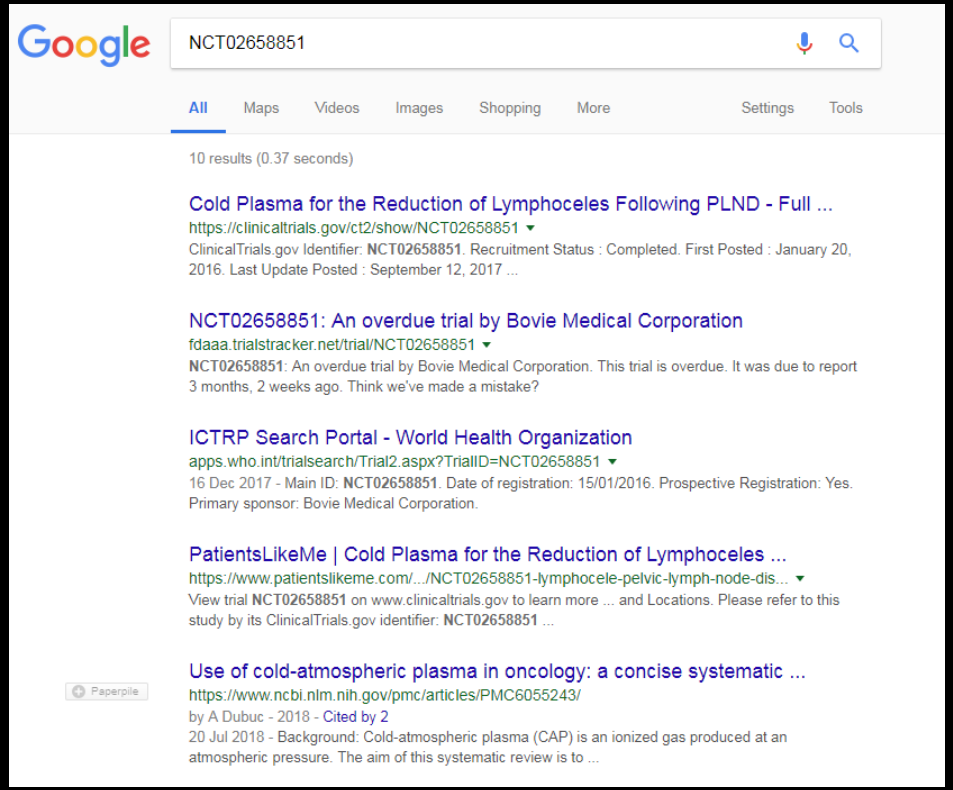

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FDAAA TrialsTracker:

A live informatics tool to monitor compliance with FDA requirements to report clinical trial results

Nicholas J. DeVito, Seb Bacon, Ben Goldacre*

EBM DataLab
University of Oxford

Abstract

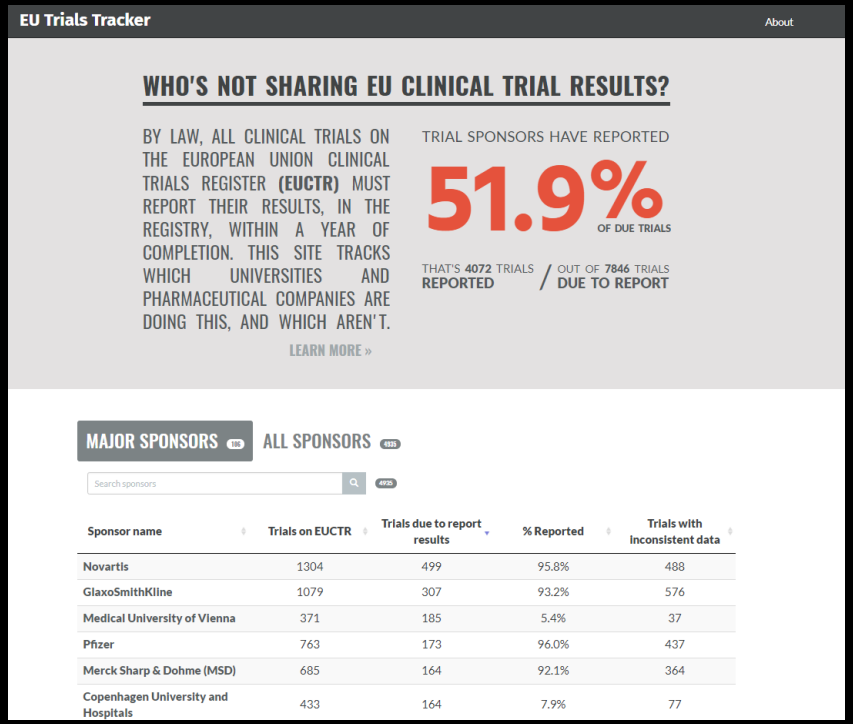
Introduction: Non-publication of clinical trials results is an ongoing issue. The US government recently updated the requirements on results reporting for trials registered at ClinicalTrials.gov. We set out to develop and deliver an online tool which publicly monitors compliance with these reporting requirements, facilitates open public audit, and promotes accountability.

Methods: We conducted a review of the relevant legislation to extract the requirements on reporting results. Specific areas of the statutes were operationalized in code based on the results of our policy review, and on the publicly available data from ClinicalTrials.gov. We developed methods to identify trials required to report results, using publicly accessible data; to download additional relevant information such as key dates and trial sponsors; and to determine when each trial became due. This data was then used to construct a live tracking website.

Results: There were a number of administrative and technical hurdles to successful operationalization in our tracker. Decisions and assumptions related to overcoming these issues are detailed along with clarifying details from outreach directly to ClinicalTrials.gov. The FDAAA TrialsTracker was successfully launched and provides users with an overview of results reporting compliance.

Discussion: Clinical trials continue to go unreported despite numerous guidelines, commitments and legal frameworks intended to address this issue. In the absence of formal sanctions from the FDA and others, we argue tools such as ours - providing live data on trial reporting - can improve accountability and performance. In addition, our service helps sponsors identify their own individual trials that have not yet reported results: we therefore offer positive practical support for sponsors who wish to ensure that all their completed trials have reported.

EU TrialsTracker



Sponsor name	Trials on EUCTR	Trials due to report results	% Reported	Trials with inconsistent data
Novartis	1304	499	95.8%	488
GlaxoSmithKline	1079	307	93.2%	576
Medical University of Vienna	371	185	5.4%	37
Pfizer	763	173	96.0%	437
Merck Sharp & Dohme (MSD)	685	164	92.1%	364
Copenhagen University and Hospitals	433	164	7.9%	77

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Commission Guideline — Guidance on posting and publication of result-related information on clinical trials in relation to the implementation of Article 57(2) of Regulation (EC) No 726/2004 and Article 41(2) of Regulation (EC) No 1901/2006

(2012/C 302/03)

1. CONTEXT

This guidance document sets out aspects of the implementation of Article 57(2), third subparagraph of Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing the European Medicines Agency [1], and of Article 41(2) of Regulation (EC) No 1901/2006 on medicinal products for paediatric use [2].

It addresses the posting and publishing of result-related information relating to clinical trials, thus implementing the EU legislation aiming to make the results of clinical trials publicly available — a policy aim which is maintained in the proposal of the Commission for a regulation of the European Parliament and of the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC [3]. This guidance document also gives guidance as to how non-compliance and factual inaccuracy are addressed.

This guidance document completes the following Commission guidance documents:

— Guideline 2010/C82/01 on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and declaration of the end of the trial (hereinafter 'detailed guidance CT-1') [4], and in particular Section 4.3 thereof,

— Guideline 2008/C168/02 on the data fields contained in the clinical trials database provided for in Article 11 of Directive 2001/20/EC to be included in the database on medicinal products provided for in Article 57 of Regulation (EC) No 726/2004 [5], and in particular Sections 3 to 5 thereof, and

— Guideline 2009/C28/01 on the information concerning paediatric clinical trials to be entered into the EU Database on Clinical Trials (EudraCT) and on the information to be made public by the European Medicines Agency (EMEA), in accordance with Article 41 of Regulation (EC) No 1901/2006 [6], and in particular Sections 3.2 to 3.4 and Section 5 thereof.

Those Commission guidance documents had been further detailed by two implementing technical guidances published in 'EudraLex — the rules governing medicinal products in the European Union' on the 'List of fields to be made public from EudraCT for Paediatric Clinical Trials in accordance with Article 41 of Regulation (EC) No 1901/2006' and the 'List of fields contained in the "EudraCT" clinical trials database to be made public, in accordance with Article 57(2) of Regulation (EC) No 726/2004.' [7].

2. SCOPE

This guidance document addresses the posting and publication of clinical trials as defined in Article 2(a) of Directive 2001/20/EC with at least one of the following characteristics:

— the clinical trial is regulated or was regulated by Directive 2001/20/EC, which took effect at the latest on 1 May 2004 (on the posting of result-related information on clinical trials which have ended in the past, see section 4.6.1). This implies that at least one investigator site of the clinical trial is located in the European Union (EU) or in a contracting State of the European Economic Area,

— the clinical trial forms part of a paediatric investigation plan including those where the investigator sites are outside the European Union (EU) [8],

— the clinical trial falls within Article 45 of Regulation (EC) No 1901/2006,

— the clinical trial falls within Article 46 of Regulation (EC) No 1901/2006.

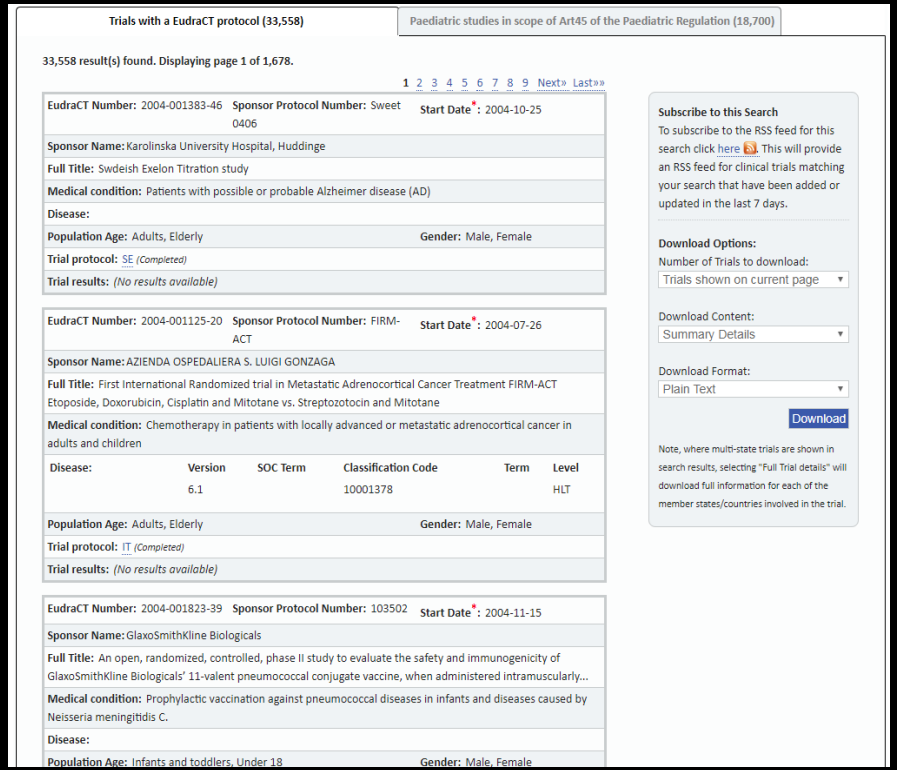
3. CONTENT OF POSTED RESULT-RELATED INFORMATION

The result-related information should be posted in accordance with this Guideline for all clinical trials referred to in Section 2.

The content of the results-related information is set out in the Guideline 2009/C28/01. The information set out there applies for paediatric as well as non-paediatric clinical trials.

The implementing technical guidance on the format of the data fields (hereinafter 'full data set') is published in a separate

[1] OJ L 136, 30.4.2004, p. 1.
[2] OJ L 378, 27.12.2006, p. 1.
[3] COM(2012) 369 final, 17.7.2012.
[4] OJ C 82, 30.3.2010, p. 1.
[5] OJ C 168, 3.7.2008, p. 3.
[6] OJ C 28, 4.2.2009, p. 1.
[7] http://ec.europa.eu/health/documents/eudralex/vol-10/index_en.htm
[8] Article 41(1) of Regulation (EC) No 1901/2006.



Trials with a EudraCT protocol (33,558) | Paediatric studies in scope of Art45 of the Paediatric Regulation (18,700)

33,558 result(s) found. Displaying page 1 of 1,678.

1 2 3 4 5 6 7 8 9 Next» Last»»

EudraCT Number: 2004-001383-46 **Sponsor Protocol Number:** Sweet 0406 **Start Date*:** 2004-10-25

Sponsor Name: Karolinska University Hospital, Huddinge

Full Title: Swdeish Exelon Titration study

Medical condition: Patients with possible or probable Alzheimer disease (AD)

Disease:

Population Age: Adults, Elderly **Gender:** Male, Female

Trial protocol: SE *(Completed)*

Trial results: *(No results available)*

EudraCT Number: 2004-001125-20 **Sponsor Protocol Number:** FIRM-ACT **Start Date*:** 2004-07-26

Sponsor Name: AZIENDA OSPEDALIERA S. LUIGI GONZAGA

Full Title: First International Randomized trial in Metastatic Adrenocortical Cancer Treatment FIRM-ACT Etoposide, Doxorubicin, Cisplatin and Mitotane vs. Streptozotocin and Mitotane

Medical condition: Chemotherapy in patients with locally advanced or metastatic adrenocortical cancer in adults and children

Disease:	Version	SOC Term	Classification Code	Term	Level
	6.1		10001378		HLT

Population Age: Adults, Elderly **Gender:** Male, Female

Trial protocol: IT *(Completed)*

Trial results: *(No results available)*

EudraCT Number: 2004-001823-39 **Sponsor Protocol Number:** 103502 **Start Date*:** 2004-11-15

Sponsor Name: GlaxoSmithKline Biologicals

Full Title: An open, randomized, controlled, phase II study to evaluate the safety and immunogenicity of GlaxoSmithKline Biologicals' 11-valent pneumococcal conjugate vaccine, when administered intramuscularly...

Medical condition: Prophylactic vaccination against pneumococcal diseases in infants and diseases caused by Neisseria meningitidis C.

Disease:

Population Age: Infants and toddlers, Under 18 **Gender:** Male, Female

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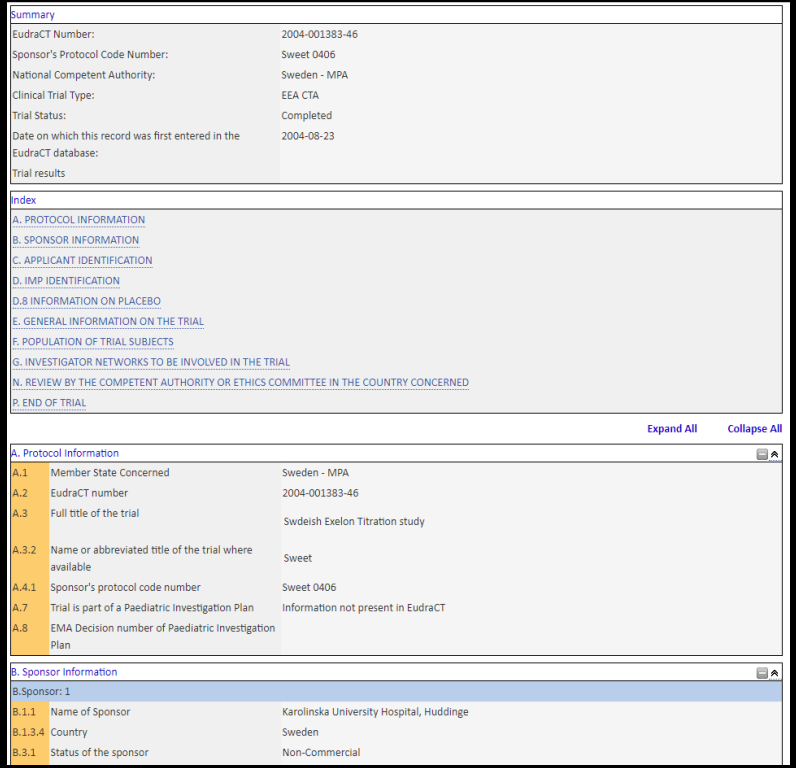
Note, where multi-state trials are shown in search results, selecting "Full Trial details" will download full information for each of the member states/countries involved in the trial.



Summary

EudraCT Number:	2004-001383-46
Sponsor's Protocol Code Number:	Sweet 0406
National Competent Authority:	Sweden - MPA
Clinical Trial Type:	EEA CTA
Trial Status:	Completed
Date on which this record was first entered in the EudraCT database:	2004-08-23
Trial results	

Index

A. PROTOCOL INFORMATION
B. SPONSOR INFORMATION
C. APPLICANT IDENTIFICATION
D. IMP IDENTIFICATION
D.8 INFORMATION ON PLACEBO
E. GENERAL INFORMATION ON THE TRIAL
F. POPULATION OF TRIAL SUBJECTS
G. INVESTIGATOR NETWORKS TO BE INVOLVED IN THE TRIAL
N. REVIEW BY THE COMPETENT AUTHORITY OR ETHICS COMMITTEE IN THE COUNTRY CONCERNED
P. END OF TRIAL

Expand All Collapse All

A. Protocol Information

A.1	Member State Concerned	Sweden - MPA
A.2	EudraCT number	2004-001383-46
A.3	Full title of the trial	Swdeish Exelon Titration study
A.3.2	Name or abbreviated title of the trial where available	Sweet
A.4.1	Sponsor's protocol code number	Sweet 0406
A.7	Trial is part of a Paediatric Investigation Plan	Information not present in EudraCT
A.8	EMA Decision number of Paediatric Investigation Plan	

B. Sponsor Information

B.Sponsor: 1		
B.1.1	Name of Sponsor	Karolinska University Hospital, Huddinge
B.1.3.4	Country	Sweden
B.3.1	Status of the sponsor	Non-Commercial

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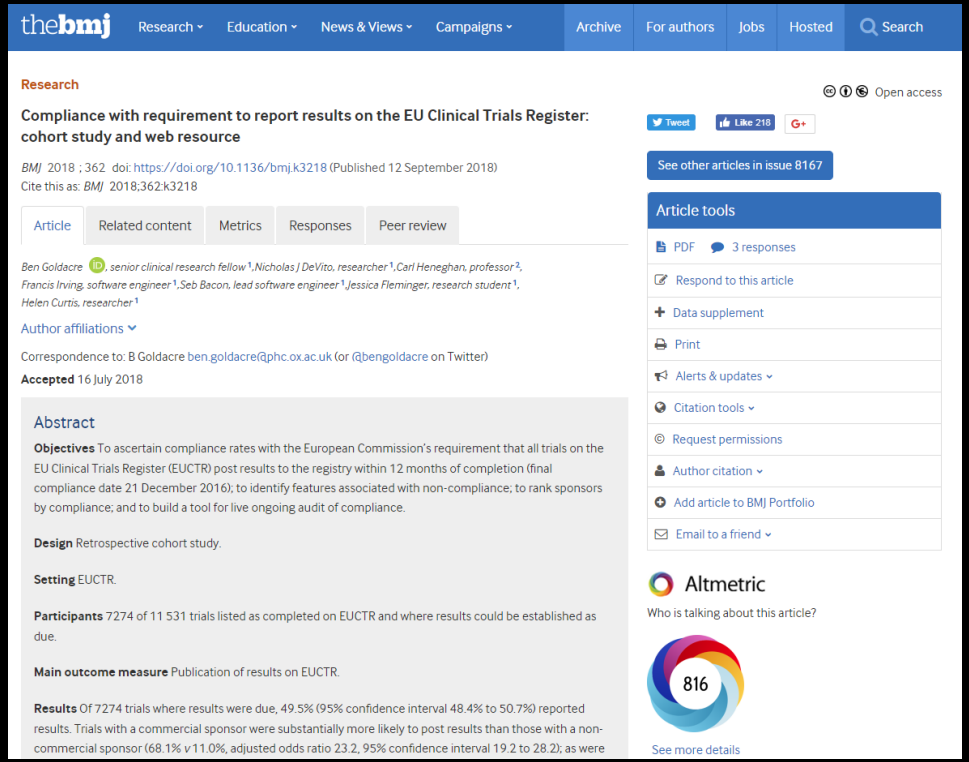
Be Conservative!

Be Transparent About Assumptions!



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Research

Compliance with requirement to report results on the EU Clinical Trials Register: cohort study and web resource

BMJ 2018 ; 362 doi: https://doi.org/10.1136/bmj.k3218 (Published 12 September 2018)
Cite this as: BMJ 2018;362:k3218

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Ben Goldacre, senior clinical research fellow [1], Nicholas J DeVito, researcher [1], Carl Heneghan, professor [2], Francis Irving, software engineer [1], Seb Bacon, lead software engineer [1], Jessica Fleminger, research student [1], Helen Curtis, researcher [1]

Author affiliations

Correspondence to: B Goldacre ben.goldacre@phc.ox.ac.uk (or @bengoldacre on Twitter)

Accepted 16 July 2018

Abstract

Objectives To ascertain compliance rates with the European Commission's requirement that all trials on the EU Clinical Trials Register (EUCTR) post results to the registry within 12 months of completion (final compliance date 21 December 2016); to identify features associated with non-compliance; to rank sponsors by compliance; and to build a tool for live ongoing audit of compliance.

Design Retrospective cohort study.

Setting EUCTR.

Participants 7274 of 11 531 trials listed as completed on EUCTR and where results could be established as due.

Main outcome measure Publication of results on EUCTR.

Results Of 7274 trials where results were due, 49.5% (95% confidence interval 48.4% to 50.7%) reported results. Trials with a commercial sponsor were substantially more likely to post results than those with a non-commercial sponsor (68.1% v 11.0%, adjusted odds ratio 23.2, 95% confidence interval 19.2 to 28.2); as were

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Industry is better are reporting than non-industry sponsored trials (OR 23.2 (19.2-28.2)

Sponsors with lots of trials are better than those who sponsor few trials (OR 18.4, 15.3-22.1)

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Feedback!

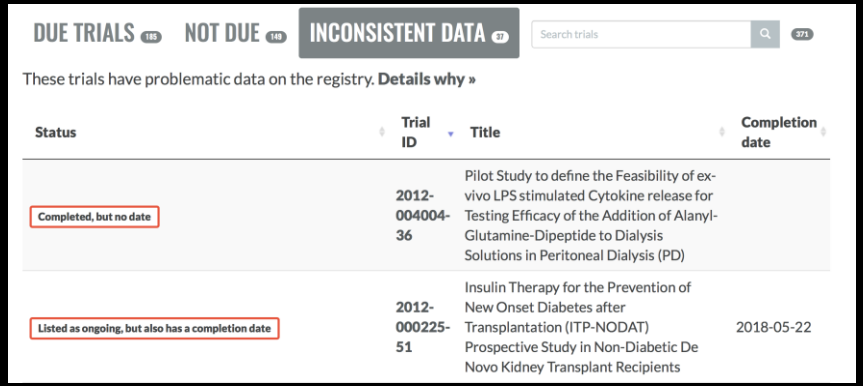
March 7, 2018 by Ben Goldacre

Our FDAAA TrialsTracker is already helping to get new trials reported!

When we launched our FDAAA TrialsTracker we wanted to produce a *tool* that would improve clinical trial reporting, rather than another repetitive academic journal paper that simply documents the extent of the problem. This reflects our ethos in the DataLab: clinicians, academics and software engineers, working together to produce tools, as well as papers.

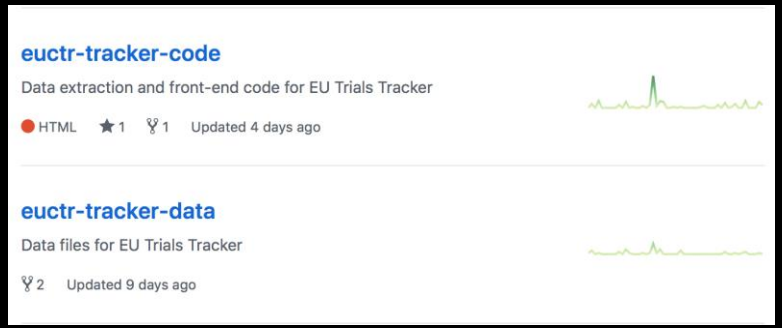
Two weeks after launch we have had extensive media coverage, and a lot of great user feedback. Here are two emails we've had from users who are employed to improve clinical trial reporting in major US institutions.

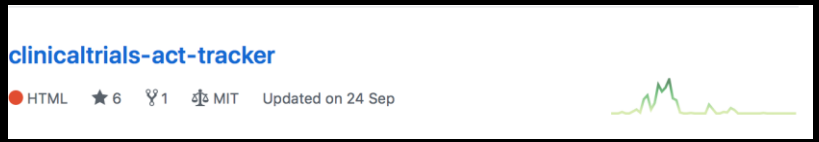
Firstly, Anthony Keyes of the Johns Hopkins School of Medicine Institute for Clinical and Translational Research wrote, explaining how our FDAAA TrialsTracker helped him find a trial that was about to go overdue, which they would otherwise have missed:



GitHub


EBM Data Lab
Evidence-Based Medicine Data Lab, University of Oxford
Oxford, UK
https://ebmdatalab.net
tech@ebmdatalab.net
Repositories 70
People 13
Teams 1
Projects 4


euctr-tracker-code
Data extraction and front-end code for EU Trials Tracker
HTML
1
1
Updated 4 days ago
euctr-tracker-data
Data files for EU Trials Tracker
2
Updated 9 days ago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1
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Updated on 24 Sep

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