

# Publikowanie wyników badań niekomercyjnych: kontekst regulacyjny a naukowy

**dr med. Piotr Iwanowski**

Stowarzyszenie na Rzecz Dobrej Praktyki Badań Klinicznych  
w Polsce

# Publikacja wyników badań: kontekst bioetyczny i naukowy

*„35. Każde badanie naukowe prowadzone z udziałem ludzi jeszcze przed rekrutacją pierwszego uczestnika musi być zarejestrowane w publicznie dostępnej bazie danych.”*

*„36. Badacze, autorzy, sponsorzy, redaktorzy i wydawcy mają moralne obowiązki związane z publikowaniem i rozpowszechnianiem wyników badań naukowych. [...] Należy publikować lub w inny sposób udostępniać publicznie zarówno wyniki pozytywne jak i negatywne oraz wyniki nierozstrzygające. [...]*

Deklaracja Helsińska Światowego Stowarzyszenia Lekarzy (WMA)

# Publikacja wyników badań: kontekst bioetyczny i naukowy



# Publikacja wyników badań: kontekst bioetyczny i naukowy

## *WHO Statement on Public Disclosure of Clinical Trial Results (2015)*

Obawy o  
wybiórcze  
publikowanie  
wyników  
badań  
klinicznych w  
zależności od  
uzyskanych  
wyników  
(*publication bias*)

Wyniki sporego  
odsetka badań  
pozostają  
nie dostępne  
jeszcze wiele  
lat po ich  
zakończeniu

**WHO Statement on Public Disclosure of Clinical Trial Results**

**Background**

Following a ministerial summit on Health Research in 2004, a World Health Assembly Resolution passed in 2005 called for unambiguous identification of all interventional clinical trials. This led to the establishment of the WHO International Clinical Trials Registry Platform, which collates information on trials that have been notified in a network of clinical trial registries ([who.int/ictrp/network](http://who.int/ictrp/network)). WHO's existing position on registration is available at [who.int/ictrp](http://who.int/ictrp): "The registration of all interventional trials is a scientific, ethical and moral responsibility". Deposition of information on trials in such registries, prior to their initiation, is a condition for publishing the results of trials in many leading medical journals<sup>1</sup>. However, concerns have been raised that there may be selective publication of trials dependent on their results, with particular concern that trial results which may be viewed as "negative", are less likely to be submitted, or accepted, for publication in the scientific literature or made public in other ways. Notification of trials to clinical trial registries has become more widespread, and it is possible to evaluate what proportions of recorded trials have not reported results at different times after the planned end dates of the trials. Multiple analyses have confirmed that a substantial number of clinical trials remain unreported several years after study completion, even in the case of large randomized clinical trials.

In the latest version of the Declaration of Helsinki it is stated that "Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first

# Publikacja wyników badań: kontekst bioetyczny i naukowy

**+ AllTrials**

All Trials Registered | All Results Reported

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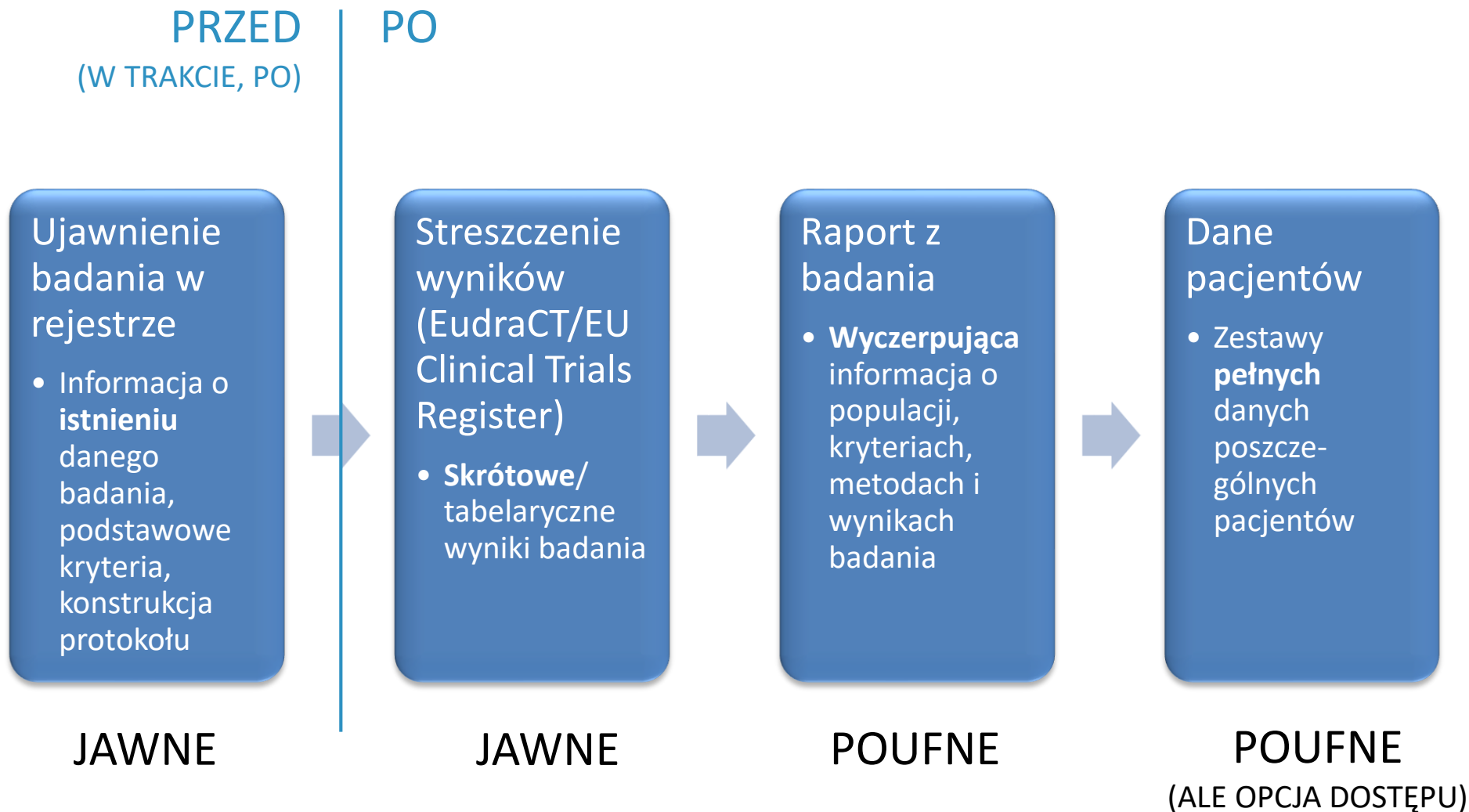
All trials		3.0%
Published trials		-16.1%
Trial 1	Trial 2	Trial 3
10.7%	-1.9%	-10.7%
<input type="checkbox"/> Publish?	<input type="checkbox"/> Publish?	<input checked="" type="checkbox"/> Publish?
Trial 4	Trial 5	Trial 6
-21.0%	-3.8%	3.7%
<input checked="" type="checkbox"/> Publish?	<input type="checkbox"/>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

**The Economist**

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

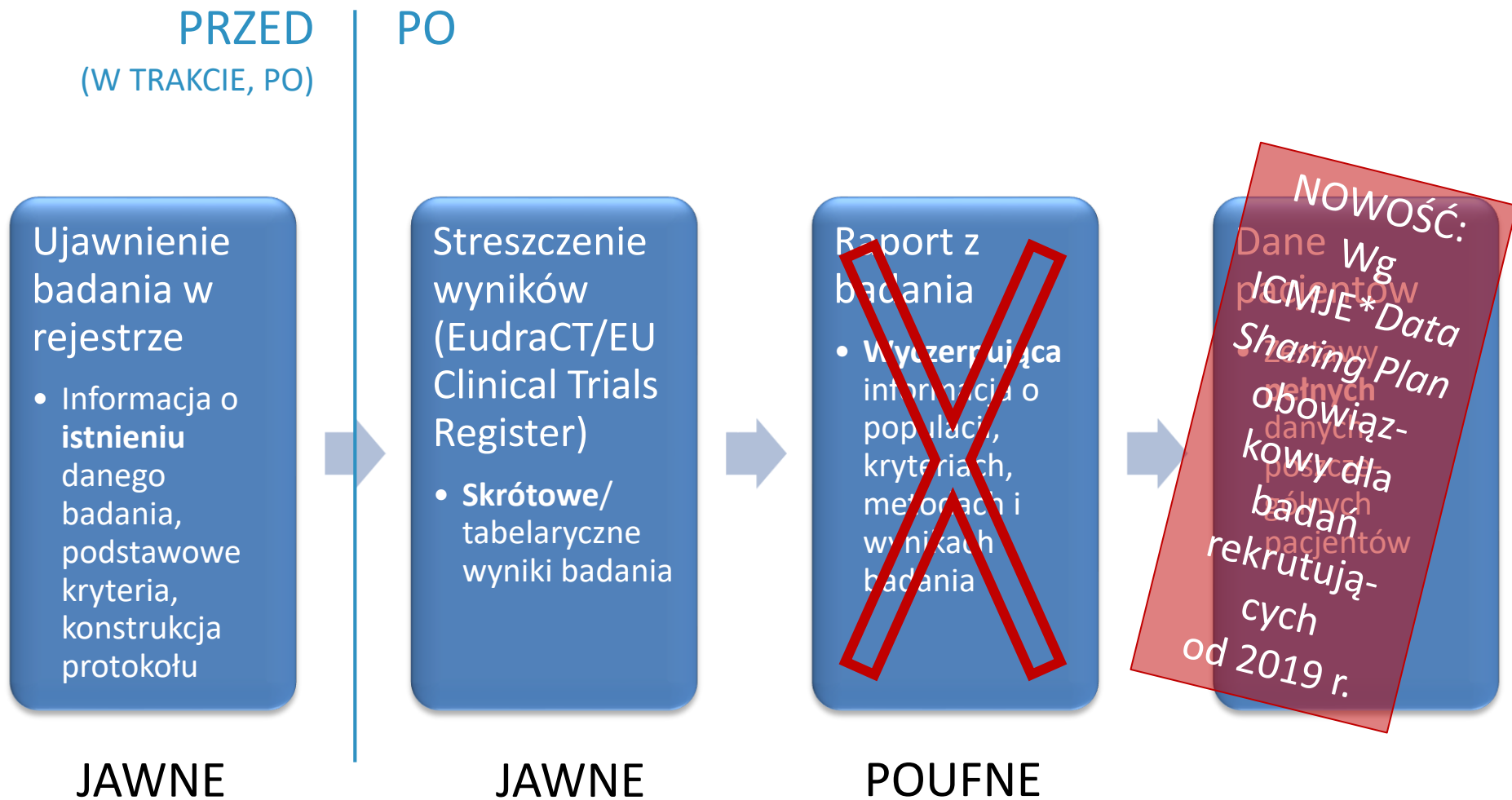
Play the game

# Cztery kategorie informacji o badaniu klinicznym: kontekst regulacyjny (badania komercyjne)



# Cztery kategorie informacji o badaniu klinicznym:

kontekst regulacyjny (badania **niekomercyjne**)



# Rejestry: EU Clinical Trials Register

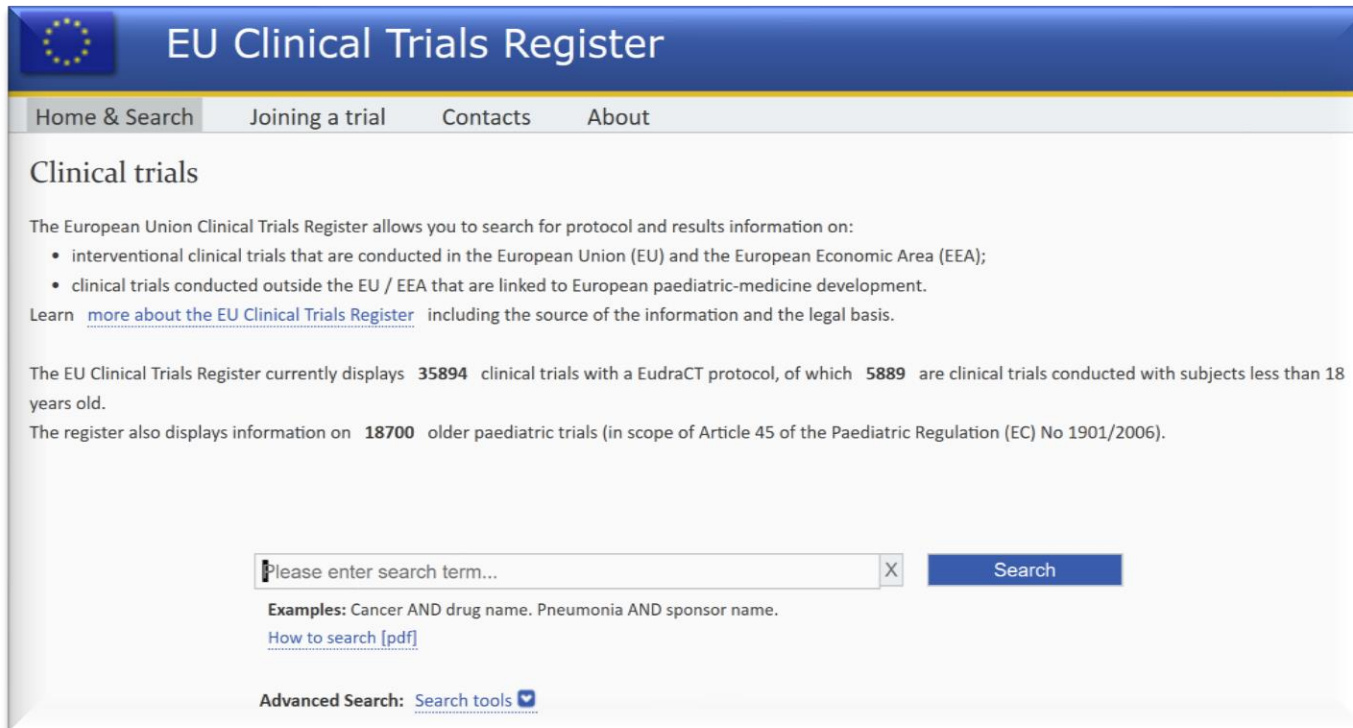
## [www.clinicaltrialsregister.eu](http://www.clinicaltrialsregister.eu)

Uruchomiony w 2011 r., obejmuje badania rozpoczęte po 1 maja 2004 r.  
Tylko badania kliniczne interwencyjne, Z ośrodkami/ośrodkiem w UE/EOG

Tylko faza II do IV

Obejmuje wybrane pola z bazy EudraCT (baza niejawna)

Dane wprowadzają (przez EudraCT) odnośne agencje lekowe narodowe



The screenshot shows the homepage of the EU Clinical Trials Register. At the top, there is a blue header with the European Union flag and the text "EU Clinical Trials Register". Below the header, there are navigation tabs: "Home & Search", "Joining a trial", "Contacts", and "About". The main content area is titled "Clinical trials" and contains the following text:

The European Union Clinical Trials Register allows you to search for protocol and results information on:

- interventional clinical trials that are conducted in the European Union (EU) and the European Economic Area (EEA);
- clinical trials conducted outside the EU / EEA that are linked to European paediatric-medicine development.

Learn [more about the EU Clinical Trials Register](#) including the source of the information and the legal basis.

The EU Clinical Trials Register currently displays **35894** clinical trials with a EudraCT protocol, of which **5889** are clinical trials conducted with subjects less than 18 years old.

The register also displays information on **18700** older paediatric trials (in scope of Article 45 of the Paediatric Regulation (EC) No 1901/2006).

At the bottom, there is a search bar with the placeholder text "Please enter search term..." and a "Search" button. Below the search bar, there are examples of search terms: "Examples: Cancer AND drug name. Pneumonia AND sponsor name." and a link to "How to search [pdf]". At the very bottom, there is a link to "Advanced Search: Search tools" with a dropdown arrow.

Nie jest portalem  
pierwotnie  
dla pacjentów

Tylko w jęz.  
angielskim

Zawiera (powinien)  
streszczenia  
wyników badań



# Rejestry: ClinicalTrials.gov

## www.clinicaltrials.gov



Rejestr amerykański, prowadzony przez U.S. National Library of Medicine.

Zawiera bardzo wiele badań prowadzonych poza USA

Zawiera też badania fazy I, badania nieinterwencyjne, epidemiologiczne i inne

Pełni nieformalnie rolę „rejestru światowego”

The screenshot shows the ClinicalTrials.gov website. At the top, there is a navigation bar with the NIH logo and the text "U.S. National Library of Medicine". Below this is the "ClinicalTrials.gov" logo. To the right of the logo are several menu items: "Find Studies", "About Studies", "Submit Studies", "Resources", and "About Site".

Below the navigation bar is a blue banner with the text: "ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world."

On the left side of the page, there is a section titled "Explore 319,963 research studies in all 50 states and in 209 countries." Below this, there is a paragraph: "ClinicalTrials.gov is a resource provided by the U.S. National Library of Medicine." followed by an "IMPORTANT" notice: "Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details." and another paragraph: "Before participating in a study, talk to your health care provider and learn about the risks and potential benefits."

On the right side of the page, there is a search form titled "Find a study (all fields optional)". The form has several sections:

- Status**: A radio button for "Recruiting and not yet recruiting studies" and a selected radio button for "All studies".
- Condition or disease**: A text input field with a placeholder "(For example: breast cancer)" and a clear button "X".
- Other terms**: A text input field with a placeholder "(For example: NCT number, drug name, investigator name)" and a clear button "X".
- Country**: A dropdown menu with a clear button "X".

At the bottom of the search form, there is a blue "Search" button and a link for "Advanced Search".

# Publikacja streszczenia wyników badania



6.10.2012

EN

Official Journal of the European Union

C 302/7

**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)

Z dniem 21.07.2014 r. stało się obowiązkowe publikowanie streszczeń wyników europejskich badań klinicznych w bazie EudraCT

Dotyczy wstecznie wszystkich badań z pozwoleniem od 2004 r.

Termin publikacji:  
do 1 roku po zakończeniu badania

# Publikacja streszczenia wyników badania (przykład)

Trials with a EudraCT protocol (1)

Paediatric studies in scope of Art

1 result(s) found for: nafithromycin. Displaying page 1 of 1.

EudraCT Number: 2016-001246-26 Sponsor Protocol Number: W-4873- Start Date: 201

Sponsor Name: Wockhardt Bio AG

Full Title: A Phase II, Randomized, Double-Blind, Multicenter, Comparative Study to Determine the Tolerability, Pharmacokinetics and Efficacy of Oral Nafithromycin Versus Oral Moxifloxacin in Adults with Community-Acquired Bacterial Pneumonia (CABP)

Medical condition: Community-Acquired Bacterial Pneumonia

Disease:	Version	SOC Term	Classification Code	Term
	19.0	100000004862	10010120	Community acquired pneumonia

Population Age: Adults, Elderly Gender: M

Trial protocol: [LV \(Completed\)](#) [BG \(Completed\)](#)

Trial results: [View results](#)

[Download PDF](#)

## Clinical Trial Results:

A Phase II, Randomized, Double-Blind, Multicenter, Comparative Study to Determine the Tolerability, Pharmacokinetics and Efficacy of Oral Nafithromycin Versus Oral Moxifloxacin in Adults with Community-Acquired Bacterial Pneumonia (CABP) in Adults

Summary	
EudraCT number	<a href="#">2016-001246-26</a>
Trial protocol	<a href="#">LV</a> <a href="#">BG</a>
Global end of trial date	08 Jul 2017
Results information	
Results version number	v1(current)
This version publication date	18 Apr 2019
First version publication date	18 Apr 2019
Other versions	

- [Trial Information](#)
- [Subject Disposition](#)
- [Baseline Characteristics](#)
- [End Points](#)
- [Adverse Events](#)
- [More Information](#)

# Clinical data sharing w badaniach komercyjnych

*More data  
has been  
created in  
the last two  
years than in  
the entire  
previous  
history of the  
human race*



Przejrzystość:  
poprawa  
społecznego  
rozumienia  
decyzji Agencji

Unikanie  
powielania  
takich samych  
badań

Możliwość  
ponownej  
pracy na  
danych przez  
innych badaczy

Zachęta do  
rozwoju  
kolejnych  
leków

Źródło: G. Zajęc, A. Pszczółkowska, AstraZeneca



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

2 October 2014  
EMA/240810/2013

*European Medicines Agency policy on publication of  
clinical data for medicinal products for human use*

# Clinical data sharing w badaniach komercyjnych



[Home](#) [Find Clinical Data](#) [About](#)



**Data on this website**

This website contains clinical data published under the European Medicines Agency (EMA) policy on the publication of clinical data. The clinical data have been submitted by pharmaceutical companies to support their marketing applications for human

**Latest clinical data published**

[Inovelon](#) (RUFINAMIDE)  
EMA/H/C/000660/II/0037 published 4 December 2018

[Ameluz](#) (5-AMINOLEVULINIC ACID)  
EMA/H/C/002204/II/0020 published 12

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# Clinical data sharing w badaniach komercyjnych

ClinicalStudy  
DataRequest.com

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**3089** Studies Listed for Data Sharing  
**531** Proposals Submitted  
**260** Proposals with Data Access Provided  
**52** Proposals Published

[See All Metrics Here](#)



AstraZeneca Group of Companies – Data Request Portal

the YODA PROJECT   Forging a unified scientific community

Discovery consists of looking at the same thing as everyone else and thinking something different.  
*Albert Szent-Györgyi*

OUR MISSION   OUR MODEL   REQUEST DATA

Navigation: ABOUT, REQUEST, TRIALS, FAQs, LOG IN

- Policies & Procedures
- Project Leadership
- Steering Committee
- Roles & Responsibilities
- Data Holders
- Publications & Presentations
- Announcements & Media Coverage
- Relevant Literature
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The Yale University Open Data Access (YODA) Project's mission is to advocate for

The YODA Project seeks mutually beneficial partnerships with Data Holders,

Are you ready to request data? To date, 184 trials have been identified as available.

AstraZeneca Group of Companies – Data Request Portal

- AstraZeneca's Transparency Policy
- Getting Started
- How to Submit a Request
- Privacy and Disclosure Statements
- Data Sharing Agreement
- Data Access and De-Identification Methods

# Clinical data sharing a badania niekomercyjne

**ICMJE** INTERNATIONAL COMMITTEE of  
MEDICAL JOURNAL EDITORS

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## Clinical Trials

*„Clinical trials that begin enrolling participants on or after 1 January 2019 must include a data sharing plan in the trial's registration.”*

*„Data sharing statements must indicate the following:*

- whether individual deidentified participant data (including data dictionaries) will be shared (“undecided” is not an acceptable answer);*
- what data in particular will be shared;*
- whether additional, related documents will be available (e.g., study protocol, statistical analysis plan, etc.);*
- when the data will become available and for how long;*
- by what access criteria data will be shared (including with whom, for what types of analyses, and by what mechanism).”*