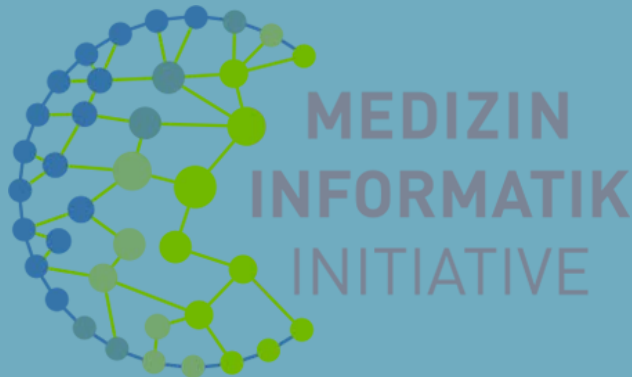


ERFAHRUNGEN ZUM DATA SHARING AUS SICHT DES QUEST CENTERS

QUEST – QUALITY | ETHICS | OPEN SCIENCE | TRANSLATION



**René Bernard
Berlin, 19. April 2018**

Workshop - Data Sharing: Kulturwandel
im Gesundheitswesen?

ÜBERBLICK

1. Was ist das QUEST Center?
2. Data Sharing: Klinische Studien
3. Data Sharing: Präklinische Studien

THIS WEEK

EDITORIALS

DRUGS New agreement to tackle pharmaceutical pollution p.184

WORLD VIEW Vaccination the best way to measure health care p.185



Let's think about cognitive bias

The human brain's habit of finding what it wants to find is a key problem for research. Establishing robust methods to avoid such bias will make results more reproducible.

Ever since I first learned about confirmation bias I've been seeing it everywhere. Some researchers already do this well, so one relatively simple strategy

Reproducibility: Seek out stronger science

• **Monya Baker**

Nature 537, 703–704



DATA SHARING

An open mind on open data

The move to make scientific findings transparent can be a major boon to research, but it can be tricky to embrace the change.

Power failure: why small sample size undermines the reliability of neuroscience

Katherine S. Putman, John D. A. Little

Repetitive flaws

Strict guidelines to improve the reproducibility of experiments are a welcome move.

From next week, scientists who submit grant applications to National Institutes of Health (NIH) will be asked to take more care. As part of an increasing drive to boost the reliability of research, the NIH will require applicants to explain the scientific premise behind their proposals and defend the quality of their experimental designs. They must also account for biological variability, for example, by including both male and female mice in planned experiments and describe how they will authenticate experimental materials as cell lines and antibodies.

These demands are timely, sensible and, if researchers have followed the advice of their scientific societies, will sound familiar. Over the past year, a string of organizations have published their statements and guidelines to boost the reproducibility of research.

Collectively, the message is: show your work, and don't fool yourself with unreliable measurements or shoddy methods. The ability to reproduce the results of your work is a fundamental requirement of science. These demands are timely, sensible and, if researchers have followed the advice of their scientific societies, will sound familiar. Over the past year, a string of organizations have published their statements and guidelines to boost the reproducibility of research. Collectively, the message is: show your work, and don't fool yourself with unreliable measurements or shoddy methods. The ability to reproduce the results of your work is a fundamental requirement of science.

Raise standards for preclinical cancer research

C. Glenn Begley and Lee M. Ellis propose how methods, publications and incentives must change if patients are to benefit.

Fewer numbers, better science

Scientific quality is hard to define, and numbers are easy to look at. But bibliometrics are warping science — encouraging quantity over quality. Leaders at two research institutions describe how they do things differently.



There are at least six things in this picture that quality assurance managers would try to improve. Can you spot them?

QUALITY TIME

IT MAY NOT BE SEXY, BUT QUALITY ASSURANCE IS BECOMING A CRUCIAL PART OF LAB LIFE.

BY MONYA BAKER

WORKPLACE CLIMATE

Metrics for ethics

Focus on perceived working conditions could help graduate schools to train responsible researchers.

THIS WEEK

EDITORIALS

POSTDOCS More pay but fewer jobs on the way p.438

WORLD VIEW Treat antibiotic resistance as an ecological crisis p.439



DRONES Tiny flying robots with power to stick around p.441

Reality check on reproducibility

A survey of Nature results. Research NATURE | NEWS

Muddled meanings hamper efforts to fix reproducibility crisis

Researchers tease out different definitions

THE LANCET

"85% of health research is wasted."

Research: increasing value, reducing waste

Acknowledging and Overcoming Nonreproducibility in Basic and Preclinical Research

Science for nonreproducibility in basic and preclinical research vs 0.71 (95% CI), original study vs 0.71 (95% CI),

biomedical research from diverse

COMMENT

nature International weekly journal of science

Home | News & Comment | Research | Careers & Jobs | Current Issue | Archive | Audio & Video

News & Comment | News | 2016 | May | Article

NATURE | NEWS

Missing mice: gaps in data plague animal research

Reports of hundreds of biomedical experiments lack essential information.



Hide results to seek the truth

More fields should, like particle physics, adopt blind analysis to thwart bias, urge Robert MacCoun and Saul Perlmutter.

Believe it or not: how much we rely on published data on power

Low statistical power in biomedical science: a review of three human research domains

Scientific method: Statistical errors

P values, the 'gold standard' of statistical validity, are not as reliable as we assume.

ROYAL SOCIETY OPEN SCIENCE

rsos.royalsocietypublishing.org

Research



Confidence in preclinical research

For decades, model organisms have provided an important reductionist approach for understanding

making strides in their efforts to understand and for the complexity of the microbiome in rodent models

DUE DILIGENCE, OVERDUE

Results of rigorous animal tests by the Amyotrophic Lateral Sclerosis Therapy Development Institute (ALSTDI) are less promising than those published. All these compounds have disappointed in human testing.

Perrin S (2014) Nature 407:423–426

Mission Statement

QUEST strebt danach, die Werthaltigkeit und den Nutzen der biomedizinischen Forschung am BIH und darüber hinaus zu erhöhen.



Education



Bio Ethics



Incentives



Open Science



Citizen Science



Meta Research

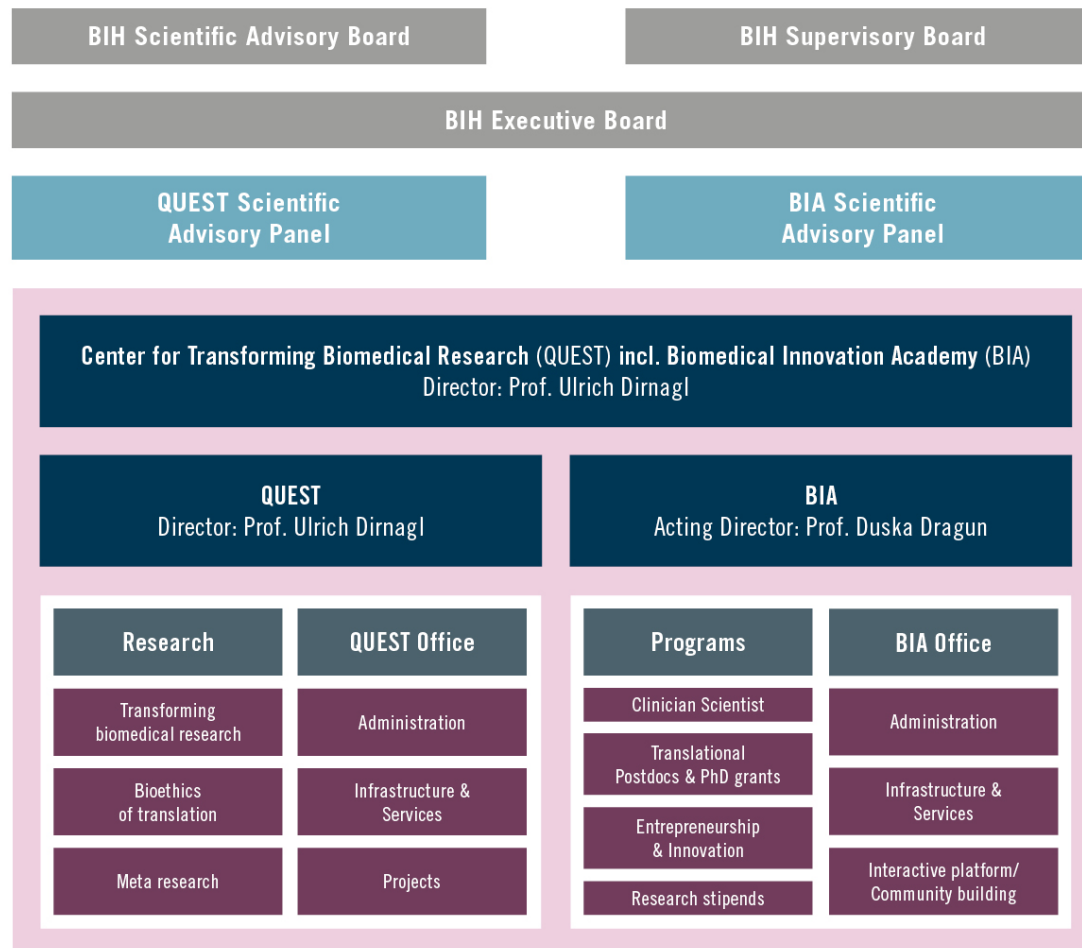


Quality



Thinktank

QUEST STRUCTURE



QUEST Wissenschaftlicher Beirat & Gastwissenschaftler

Wissenschaftlicher Beirat



Gerd Antes

Cochrane Deutschland, Freiburg, Germany



Alastair Buchan

University of Oxford, Medical School und
Medical Sciences Division, Oxford, UK



Katherine Button

University of Bath, Department of Psychology,
Bath, UK



John P.A. Ioannidis

Stanford University, School of Medicine, School
of Humanities and Sciences, Meta-Research
Innovation Center, Stanford, USA



Emily Sena

University of Edinburgh, Centre for Clinical Brain
Sciences, Edinburgh, UK

QUEST Gastwissenschaftler



Robert Nadon

The McGill University and
Genome Quebec Innovation
Centre, Canada



Mark Yarborough

UC Davis Bioethics Program,
USA

QUEST Team

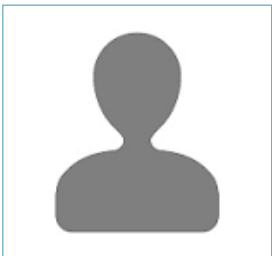
Scientific staff



Prof. Dr. Ulrich Dirnagl
BIH-Chair and QUEST Founding Director
Research Group 'Transforming
biomedical research'



**Prof. Dr. Dr. Daniel Strech (recruitment in
process: Professorship Bioethics in
Translation)**
*(Institute for History, Ethics and
Philosophy of Medicine, Hannover
Medical School)*



N.N.
Metaresearch

Office staff



Dr. Stephanie Ohlraun
Administrative Head



Lisa Liebenau
Open Science Officer



Dr. Nico Riedel
Data Scientist



Dr. Miriam Kip
Indicators & Incentives
officer



Dr. Ulf Toelch
Education officer



Dr. Klaus-Detlef Heber
IT administrator

DATA SHARING: KLINISCHE STUDIEN

1. Ethische Verpflichtung
2. Nutzen des Daten Sharing ist größer als der Aufwand
3. Vertrauen schaffen durch Teilen

ABSICHT UND REALITÄT

- Studie der Gruppe um J.loannidis (*BMJ* 2018;360:k400)
- 37 klinische Studien in Journalen mit klaren Data Sharing Policies (BMJ und PLoS)
- Nach Aufforderung: 17/37 – Daten verfügbar
- 14/17 Replikation der jeweiligen primären Endpunkte

TRANSPARENZ

- AllTrials - Data Sharing Nachverfolgung registrierter und abgeschlossener Studien
- Sichtbarkeit durch Trialtracker – Wer teilt seine klinischen Daten wirklich?



Who's not sharing their trial results?

Trials registered on [ClinicalTrials.gov](https://clinicaltrials.gov) should share results on the site shortly after completing, or publish in a journal. But many organisations fail to report the results of clinical trials. We think this should change. Explore our data (last updated April 2017) to see the universities, government bodies and pharmaceutical companies that aren't sharing their clinical trial results.

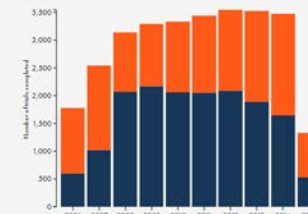
Trial sponsors

We've ranked the major trial sponsors with the most unreported trials registered on [ClinicalTrials.gov](https://clinicaltrials.gov). Click on a sponsor's name to find out whether it's getting better at reporting completed trials - or worse.

Name of sponsor	Trials missing results	Total eligible trials	Percent missing
1 Sanofi	289	457	63.2%
2 Assistance Publique - Hôpitaux de Paris	217	329	66.0%
3 Novartis Pharmaceuticals	201	577	34.8%
4 GlaxoSmithKline	184	891	20.7%
5 National Cancer Institute (NCI)	176	570	30.9%
6 Mayo Clinic	168	339	49.6%
7 Yonsei University	161	226	71.2%
8 Seoul National University Hospital	153	241	63.5%

Trials by year

Since Jan 2006, all major trial sponsors completed 29,377 eligible trials and haven't published results for 13,266 trials. That means 45.2% of their trials are missing results.



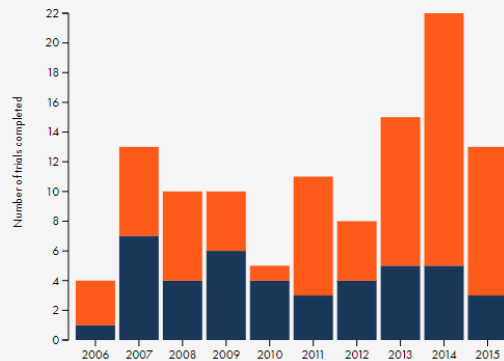
<https://trialtracker.ebmdatalab.net>

@TrialsTracker

DATA SHARING: KLINISCHE STUDIEN

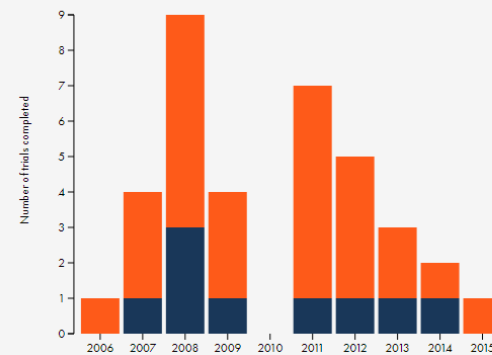
Trials by year

Since Jan 2006, **Charite University, Berlin, Germany** completed 111 eligible trials and **hasn't published results for 69 trials**. That means 62.2% of its trials are missing results. See all its completed trials on [ClinicalTrials.gov](#).



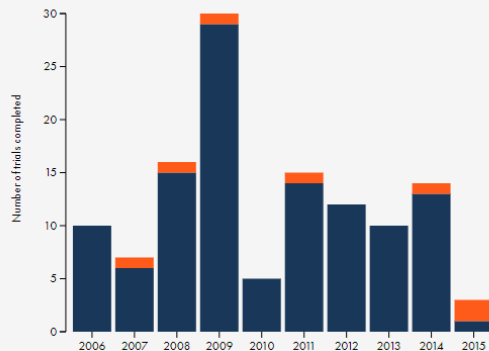
Trials by year

Since Jan 2006, **Ludwig-Maximilians - University of Munich** completed 36 eligible trials and **hasn't published results for 27 trials**. That means 75.0% of its trials are missing results. See all its completed trials on [ClinicalTrials.gov](#).



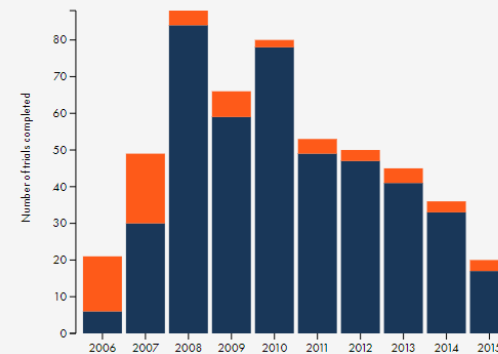
Trials by year

Since Jan 2006, **Bristol-Myers Squibb** completed 122 eligible trials and **hasn't published results for 7 trials**. That means 5.7% of its trials are missing results. See all its completed trials on [ClinicalTrials.gov](#).

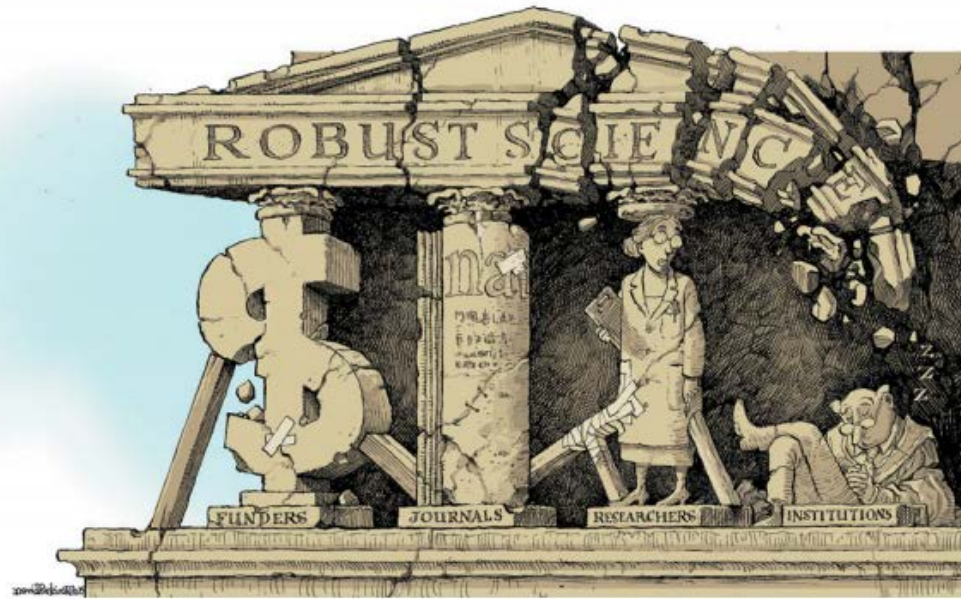


Trials by year

Since Jan 2006, **Pfizer** completed 508 eligible trials and **hasn't published results for 64 trials**. That means 12.6% of its trials are missing results. See all its completed trials on [ClinicalTrials.gov](#).



- **Institutions' contributions to increasing value** and reducing waste in biomedical research (**IntoValue**) – D.Strech, N.Riedel, QUEST
- genaue Anteil der an allen 36 deutschen Universitätskliniken durchgeführten Studien ist, zu denen keine Ergebnisse publiziert wurden (2009-2013)
- durchsucht deutsche und europäische Register; z.T. händische Suche in Monographien
- vorläufig: deutsche Studienergebnisse werden nicht zeitnah geteilt

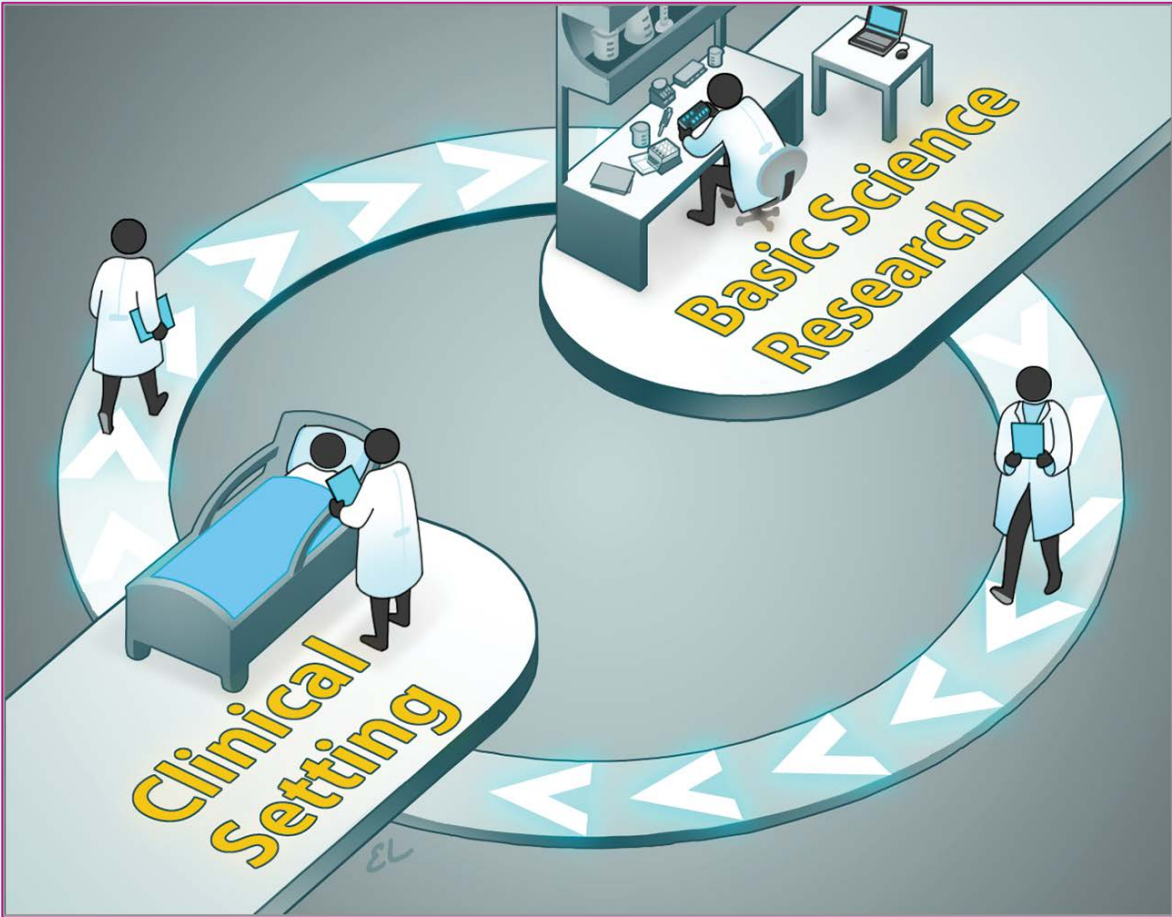


Institutions must do their part for reproducibility

Tie funding to verified good institutional practice, and robust science will shoot up the agenda, say C. Glenn Begley, Alastair M. Buchan and Ulrich Dirnagl.

Nature 525 (2015): 25-27

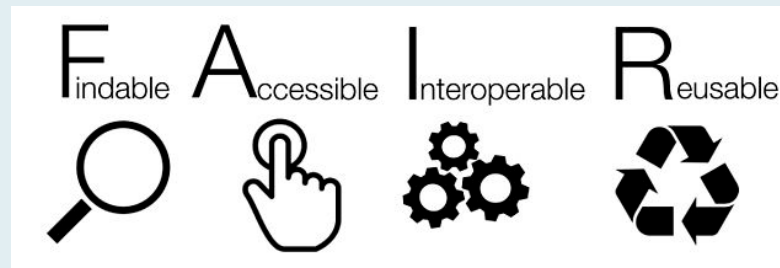
DATA SHARING: PRÄKLINISCHE STUDIEN



DISZIPLINEN MIT STANDARDISIERTE DATENREPOSITORIEN

- nucleic acid and protein sequencing
- molecular structures
- omics
- cytometry, immunology databases
- organism-focused informatics

FÜR ALLES ANDERE: DATEN ~~ABLAGEN~~ DEPONIEREN

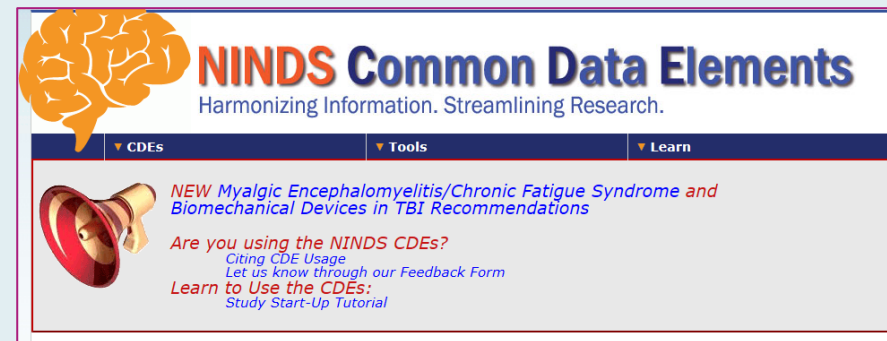
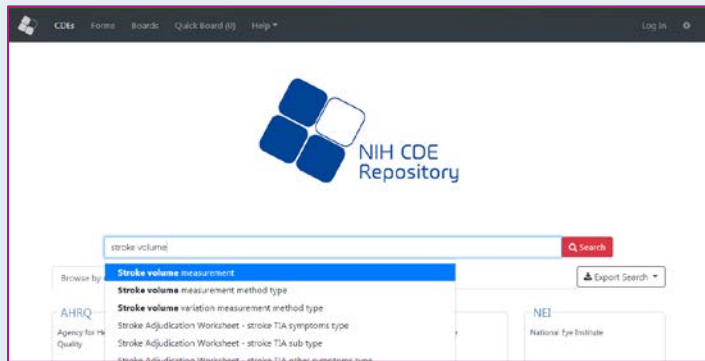


1. Undokumentiert (keine Metadaten)
2. Konsistenz & Checks der Datenqualität und –formate
3. Keine bidirektionale Verlinkung zu Veröffentlichungen
4. Bestenfalls „findable“ via DOI, aber wiederverwendbar in seltensten Fälle

DATA SHARING: PRÄKLINISCHE STUDIEN - STANDARDFORMATE

COMMON DATA ELEMENTS ALS VORBILD

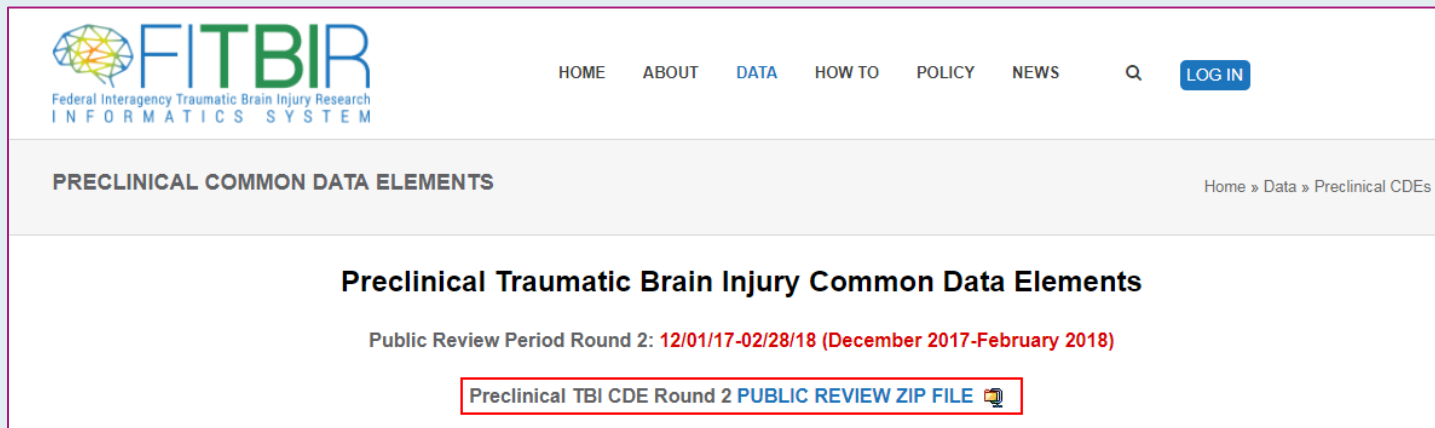
- Adaption aus der Klinik
- Standardisierte Variablen, Attribute, Maße oder Konzepte
- Können übergreifend und disziplinspezifisch sein
- Dienen als Variablen in Datenbanken
- Erleichtert den Austausch und des Teilen von Daten



DATA SHARING: PRÄKLINISCHE STUDIEN - STANDARDFORMATE

COMMUNITY BASED STANDARDS

Traumatische Hirnverletzung: Preclinical Common Data Elements



The screenshot shows the FITBIR (Federal Interagency Traumatic Brain Injury Research Informatics System) website. The header includes the FITBIR logo and navigation links: HOME, ABOUT, DATA, HOW TO, POLICY, NEWS, a search icon, and a LOG IN button. The main content area features the heading "PRECLINICAL COMMON DATA ELEMENTS" with a breadcrumb trail "Home » Data » Preclinical CDEs". Below this, the title "Preclinical Traumatic Brain Injury Common Data Elements" is displayed, followed by the text "Public Review Period Round 2: 12/01/17-02/28/18 (December 2017-February 2018)". A red-bordered box highlights a link: "Preclinical TBI CDE Round 2 PUBLIC REVIEW ZIP FILE" with a download icon.

Subklassifizierung ähnelt den klinischen CDEs
Support: NINDS CDE Team

DATA SHARING: PRÄKLINISCHE STUDIEN – STANDARDFORMATE

DISZIPLIN-SPEZIFISCHE DATENBANKEN

- Wenn Standards einmal existieren, müssen sich Communities finden und Spezialrepositorien schaffen, die auf den pCDE

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Explore Communities
Create or browse communities to explore personalized data portals for you or your group to work with

Browse Resources
Join the largest scientific resource registry and add, share, and search for new resources with your community.

Search through Data
Search across more than 200 data repositories

CREATE YOUR OWN COMMUNITY

Communities allow researchers to share and customize data from **over 200 data resources**.

 **Create**

HAUSAUFGABEN FÜR INSTITUTIONEN

- Präklinisches Datenmanagement an jeder Universität – Ablage für Rohdaten (unveränderlich)
- Aufbau institutioneller Datenrepositorien (Freigabemöglichkeit)
- Datenqualitätskontrolle (Data Stewardship)

ZUSAMMENFASSUNG

- Umfassende Ursachenanalyse
- Bessere Incentives, bessere Nachverfolgung
- Projekte mit Sichtbarkeit – positiven Nutzen des Data Sharing
- Förderung des inst. Forschungsdatenmanagements incl. Data Sharing