Cochrane Switzerland

IUMSP - Institut universitaire de médecine sociale et préventive

Studienprotokolle als Basis für transparente & vollständige Manuskripte (SPIRIT)

12. Clinical Research Forum
“Publizieren von Studienprotokollen: wozu und wie?”

Basel, 4. November 2017

Dr. Erik von Elm, MSc FMH
Cochrane Schweiz, IUMSP / CHUV Lausanne
erik.vonelm@chuv.ch

Trusted evidence.
Informed decisions.
Better health.

@CochraneSuisse

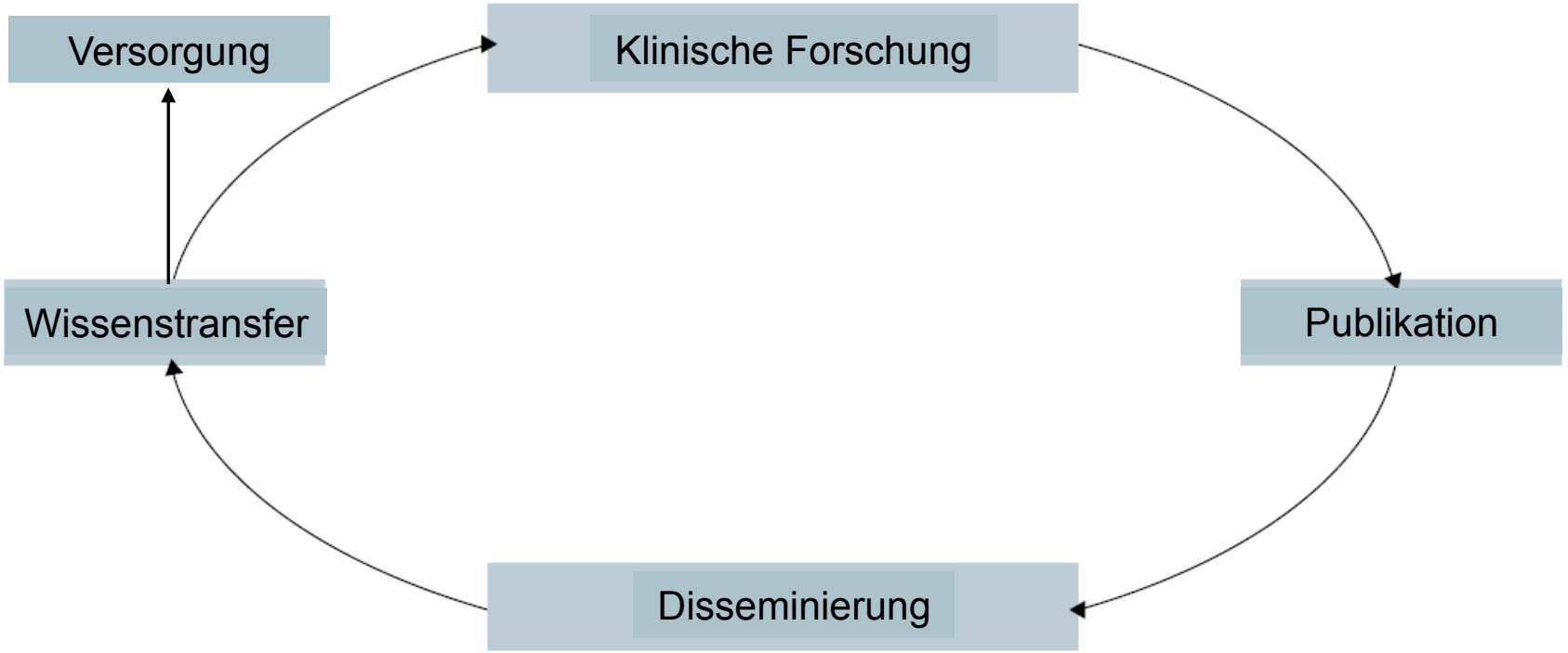
Der Verfasser eines Studienprotokolls von heute

… ist (hoffentlich) der Autor eines Artikels von morgen

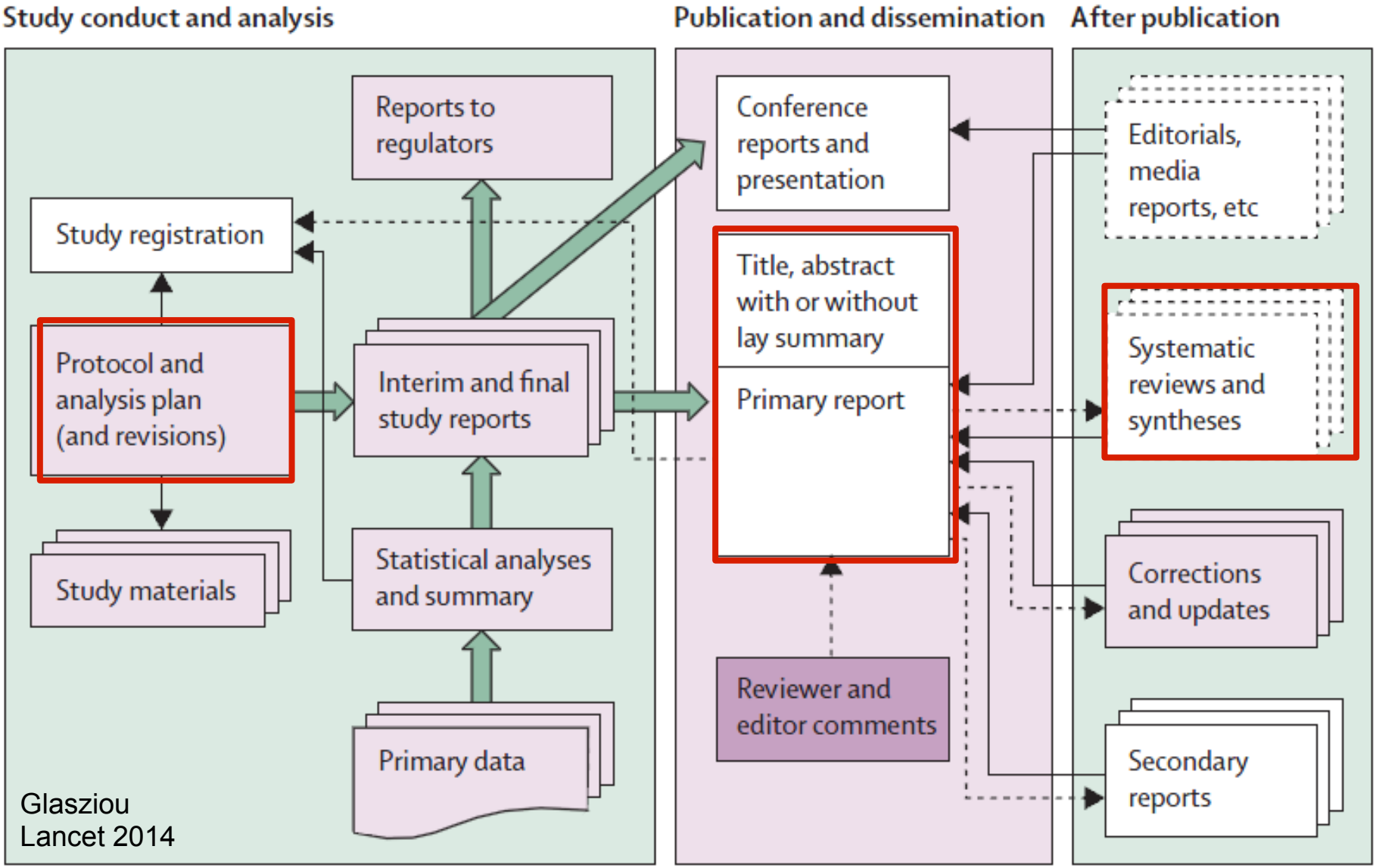
… ist (vielleicht) der Peer Reviewer von übermorgen

… ist …

Erkenntnisgewinn: mehrstufig & kumulativ



Another “big picture”



Glasziou
Lancet 2014

Studienqualität *vs.* Berichtsqualität

- Qualität der **Studienmethodik** muss von Qualität der **Studienberichte** (Reporting) unterschieden werden
  - Gute Studien, aber schlecht berichtet, z.B. unvollständig oder irreführend (Intransparenz)
  - Womöglich schlechte Studien, aber gut (z.B. ehrlich) berichtet (Transparenz)
- Ungenügende Berichtsqualität verhindert Einordnung der Wertigkeit von Studienergebnissen („high / low risk of bias“)
- Studienprotokolle: Studienmethodik steht im Vordergrund

Was wissen wir über Berichtsqualität in klinischer Forschung ?

Research on Research / Reporting / Publishing

- Empirische Studien, die Berichtsqualität publizierter klinischer Forschung analysieren, z.B. von
  - randomisierten kontrollierten Studien (RCTs)
  - anderen Studientypen (z.B. Beobachtungsstudien)
  - seltener: Qualität von Studienprotokollen
- Systematische Reviews, die empirische Daten zusammenfassen
- Studien, die Quervergleiche anstellen z.B.
  - Studienprotokolle vs. Publikationen
  - Studienregister vs. Protokolle / Publikationen

Beispiel 1:
Beschreibung der Studienintervention

Glasziou BMJ 2008

- Untersuchte wie in 80 Publikationen im Journal "*Evidence-Based Medicine*" Studienintervention beschrieben wurde
  - 55 randomisierte Studien
  - 25 systematische Reviews

- In 41 Artikeln fehlten wesentliche Elemente, um Intervention nachzuvollziehen

- Nur 3 von 25 systematische Reviews lieferten Beschreibung, die für zukünftige Implementierung ausreichend wäre

Beispiel 2:
Methoden randomisierter Studien

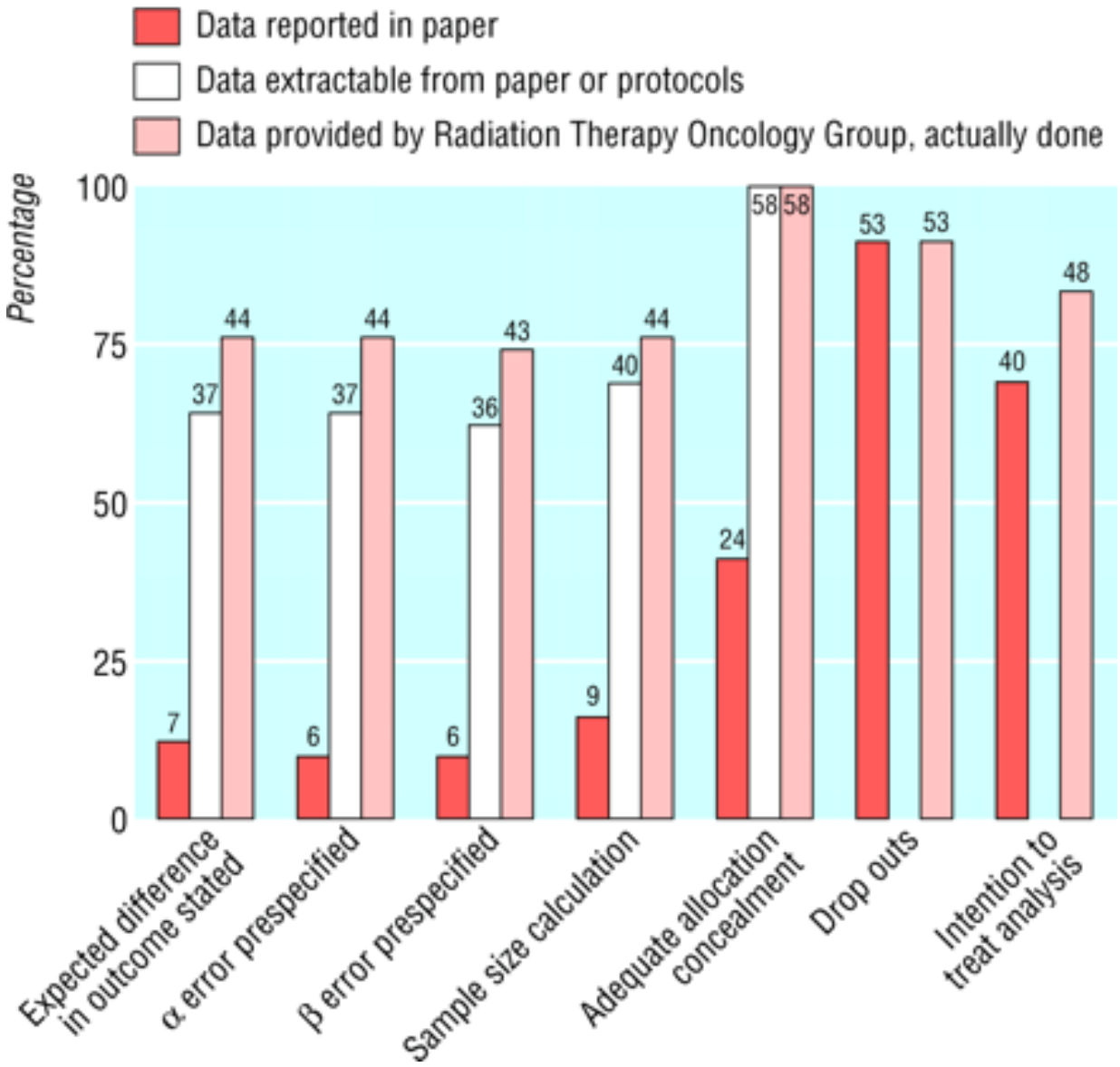
Soares BMJ 2004

56 Phase-3-Studien der Radiation Therapy Oncology Group (US + Can) seit 1968

58 zugehörige Publikationen

Vorhandene Information fehlte in Artikeln, war aber bei Forschungs-gruppe erhältlich

➔ Schlechte Publikation heisst nicht, dass Studie schlecht war in Durch-führung

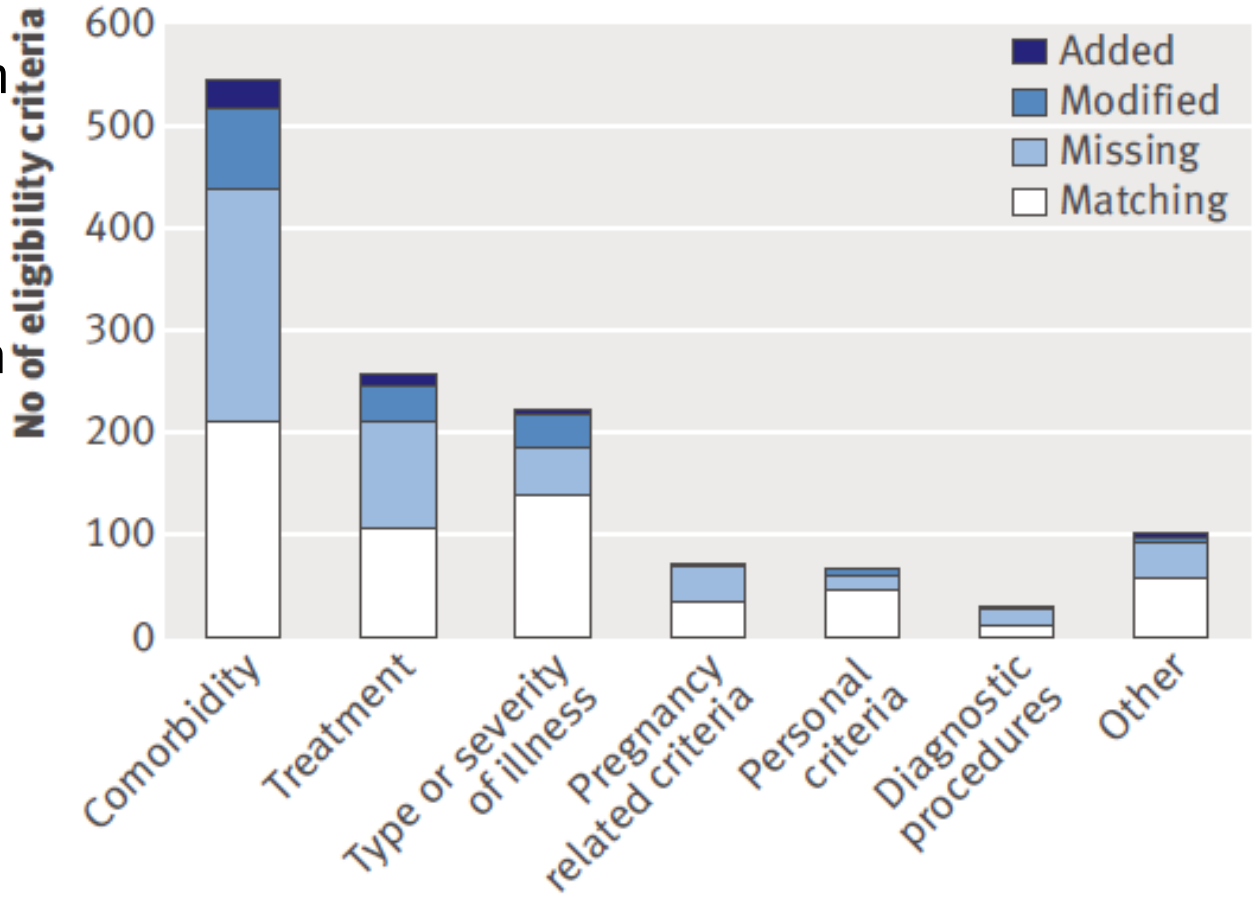


Beispiel 3:
Berichten von Ein-/ Ausschlusskriterien

Blümle et al. BMJ 2011

- 52 RCT Protokolle, im Jahr 2000 an EK Freiburg eingereicht
- 78 Publikationen
- 1299 versch. Kriterien
  - 49% identisch
  - 38% fehlend
  - 13% geändert
- 51 Kriterien waren in Artikeln neu definiert !

➔Unterschiede bei allen 52 RCTs



Number of matching, missing, modified, and added eligibility criteria (n=1299) for each content category

Beispiel 4:
Frühzeitiger Studienabbruch

Kasenda / von Elm et al. JAMA 2014

- Follow-up von 1017 Studienprotokollen von RCTs, eingereicht 2000 - 2003 bei 6 Ethik-kommissionen in CH, D, CAN
- 253 (25%) wurden frühzeitig abgebrochen
  - davon 101 (40%) wegen Rekrutierungsproblemen
- EK wussten nur von 96 der 253 Abbrüche (38%)

Amstutz et al. BMJ Open 2017

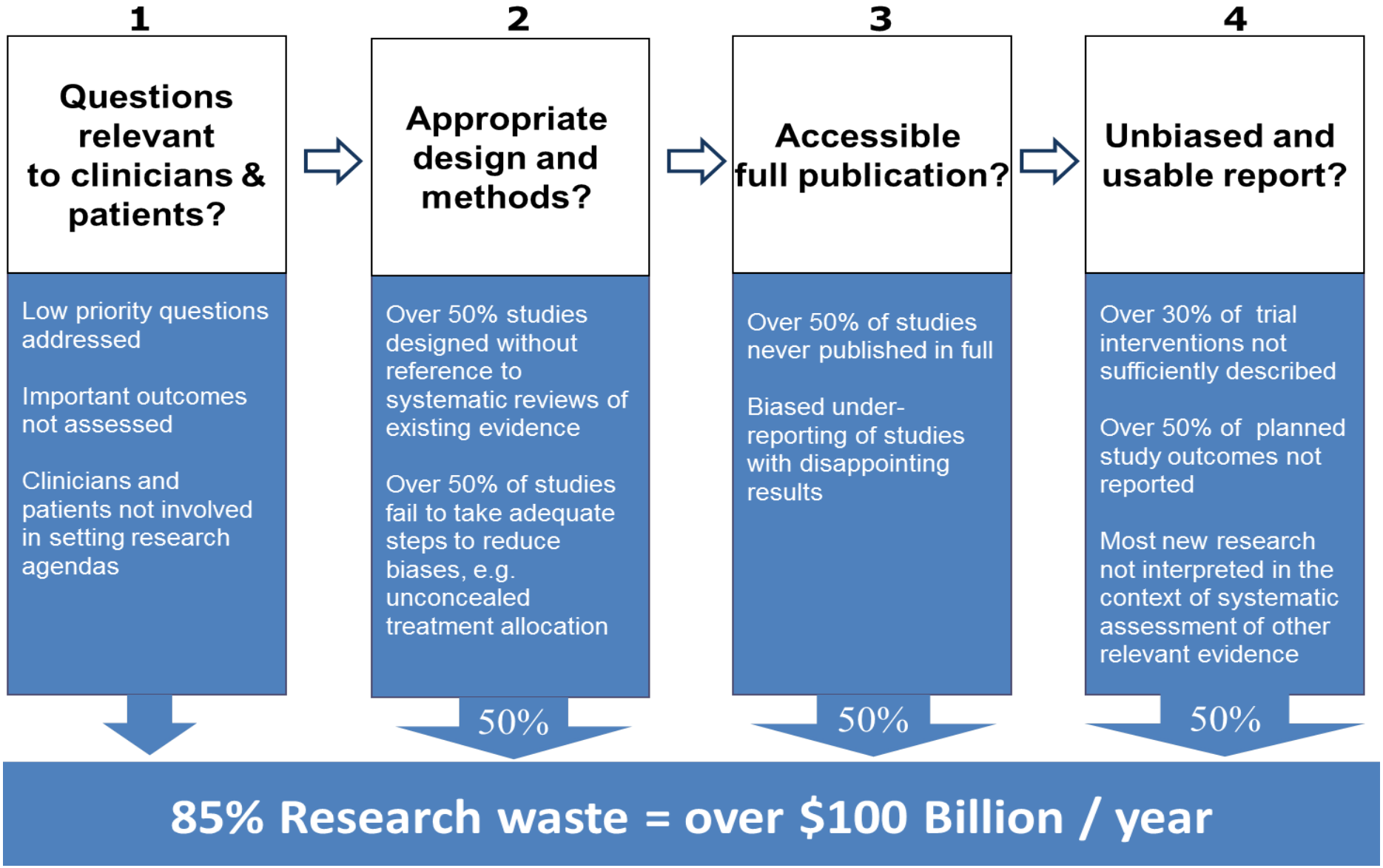
- 101 SNF-finanzierte Trials (1986 – 2015)
- 26 (26%) wurden frühzeitig abgebrochen (bei weiteren 6 unklar)
  - alle wegen Rekrutierungsproblemen
- Im Vergleich mit Trials ohne SNF-Finanzierung war Risiko für Studienabbruch nicht geringer.
- Kein zeitlicher Trend zu Verminderung von Studienabbrüchen (Verbesserung)

Forschung zu Berichtsqualität: Überblick

Abstract
Trials: missing effect size and confidence interval (38%); no mention of adverse effects (49%)[72]
Methods
Trials: 40–89% inadequate treatment descriptions[11, 13] **fMRI studies:** 33% missing number of trials and durations[3] **Survey questions:** 65% missing survey or core questions[25] **Figures:** 31% graphs ambiguous[45]
Results
Clinical trials: outcomes missing: 50% efficacy and 65% harm outcomes per trial incompletely reported[6] **Animal studies:** number of animals and raw data missing[17] (54%, 92%); age and weight missing (24%) **Diagnostic studies:** missing age and sex (40%)[15]
Discussion
Trials: no systematic attempt to set new results in context of previous trials (50%)[69]
Data
Trials: most data never made available; author-held data lost at about 7% per year

Glasziou Lancet 2014

Waste at four stages of research



Chalmers Glasziou Lancet 2009

THE LANCET

< Previous Article Volume 383, No. 9912, p166–175, 11 January 2014 Next Article >

Series

Increasing value and reducing waste in research design, conduct, and analysis

Prof John P A Ioannidis, MD, Prof Sander Greenland, DrPH, Prof Mark A Hlatky, MD, Muin J Khoury, MD, Prof Malcolm R Macleod, PhD, Prof David Moher, PhD, Prof Kenneth F Schulz, PhD, Prof Robert Tibshirani, PhD

Published: 08 January 2014

PlumX Metrics

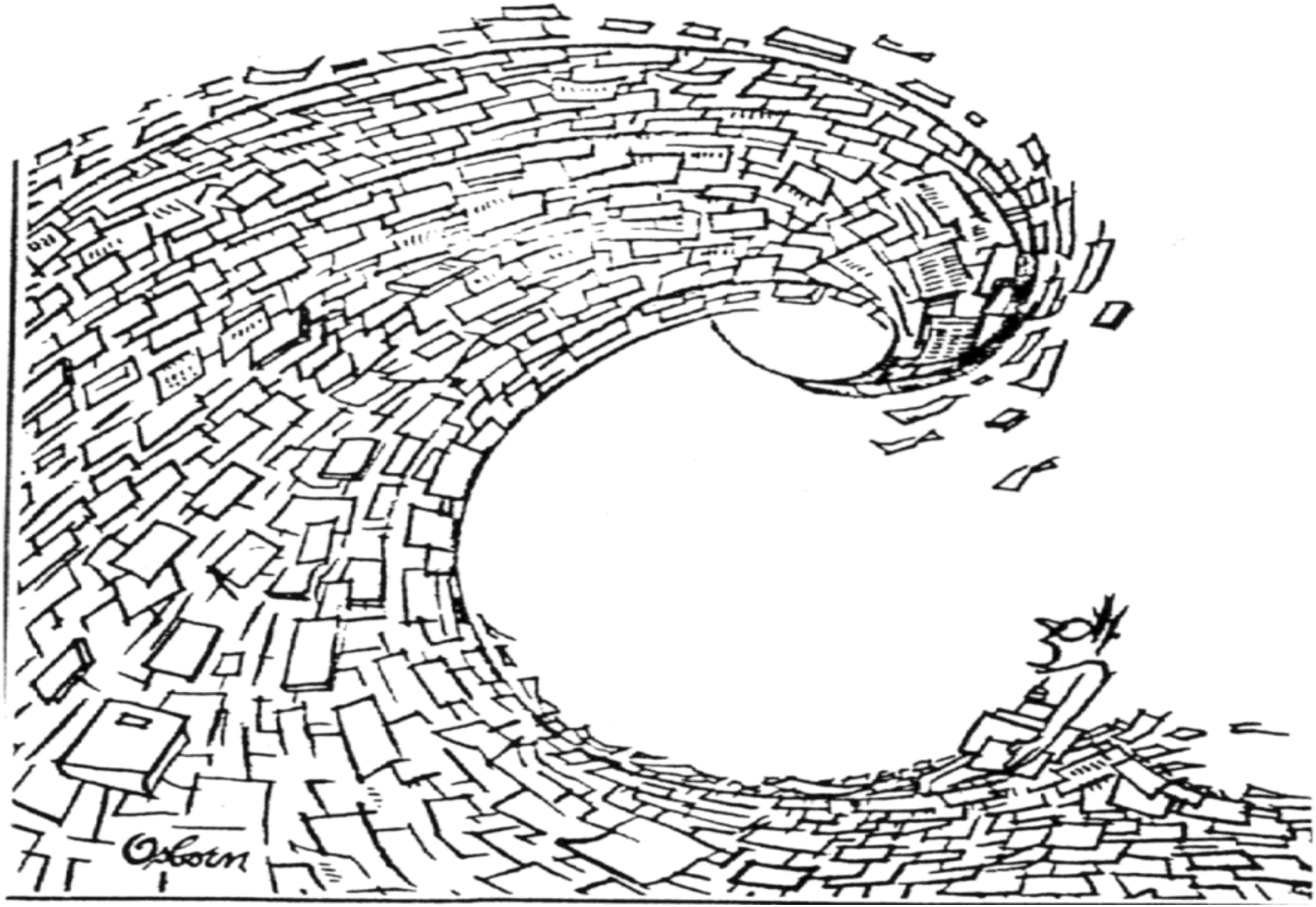
DOI: http://dx.doi.org/10.1016/S0140-6736(13)62227-8 | CrossMark

Article Info

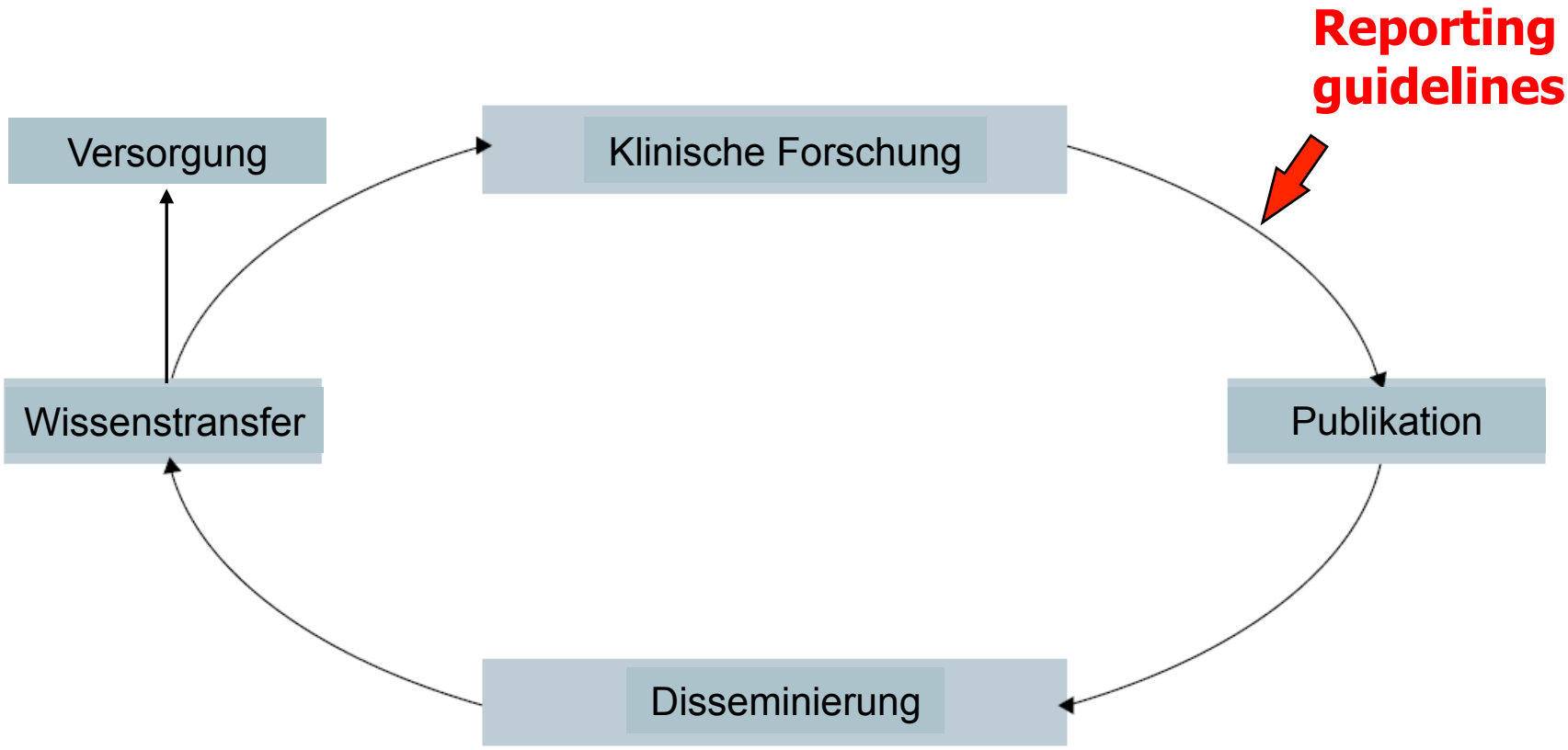
Summary

Correctable weaknesses in the design, conduct, and analysis of biomedical and public health research studies can produce misleading results and waste valuable resources. Small effects can be difficult to distinguish from bias introduced by study design and analyses. An absence of detailed written protocols and poor documentation of research is common. Information obtained might not be useful or important, and statistical precision or power is often too low or used in a misleading way. Insufficient consideration might be given to both previous and continuing studies. Arbitrary choice of analyses and an overemphasis on random extremes might affect the reported findings. Several problems relate to the research workforce, including failure to involve experienced statisticians and methodologists, failure to train clinical researchers and laboratory scientists in research methods and design, and the involvement of stakeholders with conflicts of interest. Inadequate emphasis is placed on recording of research decisions and on reproducibility of research.

Fünfteilige Lancet-Serie 2014 „Research: increasing value, reducing waste“


Osborn

Erkenntnisgewinn: mehrstufig & kumulativ



Lösungsansatz: Reporting guidelines

- Von internationalen Arbeitsgruppen erarbeitete Leitlinien für Studienberichte / -protokolle
- **Minimal-Listen** von Inhalten, um Vollständigkeit und Transparenz eines Protokolls / Manuskripts zu gewährleisten
  - Protokoll: “What is planned exactly & why ?”
  - Manuskript: “What was done & what was found ?”
- Format: Checkliste, Flussdiagramm, erklärender Text
- Fokus auf methodischen Schwächen, die zu Bias führen können
- Item-Auswahl gestützt auf empirischer Evidenz.
  Falls nicht vorhanden, Konsensus der Arbeitsgruppe

Wichtige Reporting-Guidelines

1996	CONSORT	RCTs (Revision 2001 & 2010)
2000	MOOSE	Meta-analysen observ. Studien
2003	STARD	Diagnostische Studien
2004	TREND	Nicht-randomisierte Studien
2007	STROBE	Fallkontroll / Querschnitts- / Kohortenstudien
2007	COREQ	Qualitative Forschung
2008	SQUIRE	Qualitätsverbesserungsstudien
2009	PRISMA	Syst. Reviews & Meta-analysen (ersetzt QUOROM 1999)
2013	**SPIRIT**	**Studienprotokolle von RCTs**
2015	PRISMA-P	Protokolle von syst. Reviews

Siehe: Online-Bibliothek des EQUATOR-Networks
www.equator-network.org

Search for reporting guidelines

Browse for reporting guidelines by selecting one or more of these drop-downs:

Study type: Study protocols and Clinical area: Please select... and Section of report: Please select...

Or search with free text

Search Reporting Guidelines

Start again | Help

Displaying 8 reporting guidelines found.

Key reporting guidelines, shaded green, are displayed first. Show the most recently added records first.

1. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials
2. Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 statement
3. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide
4. Development and validation of the guideline for reporting evidence-based practice educational interventions and teaching (GREET)

Reporting guidelines for main study types

Randomised trials	CONSORT	Extensions
Observational studies	STROBE	Extensions
Systematic reviews	PRISMA	Extensions
Case reports	CARE	Extensions
Qualitative research	SRQR	COREQ
Diagnostic / prognostic studies	STARD	TRIPOD
Quality improvement studies	SQUIRE	
Economic evaluations	CHEERS	
Animal pre-clinical studies	ARRIVE	
Study protocols	SPIRIT	PRISMA-P
Clinical practice guidelines	AGREE	RIGHT

Translations

Some reporting guidelines are also available in languages other than English. Find out more in our Translations section.

Search for reporting guidelines

Use your browser's Back button to return to your search results

SPIRIT 2013 Statement: Defining standard protocol items for clinical trials

Reporting guideline provided for? (i.e. exactly what the authors state in the paper)	Defining standard protocol items for clinical trials SPIRIT 2013 checklist (Word)
Full bibliographic reference	Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-207.
Language	English
PubMed ID	23295957
Relevant URLs (full-text if available)	The full-text of the SPIRIT 2013 Statement is available from: http://www.spirit-statement.org/publications-downloads/
Explanation and elaboration papers	Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin J, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleža-Jerić K, Laupacis A, Moher D. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. BMJ. 2013;346:e7586. PMID: 23303884

Reporting guidelines for main study types

Randomised trials	CONSORT	Extensions
Observational studies	STROBE	Extensions
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Qualitative research	SRQR	COREQ
Diagnostic / prognostic studies	STARD	TRIPOD
Quality improvement studies	SQUIRE	
Economic evaluations	CHEERS	
Animal pre-clinical studies	ARRIVE	
Study protocols	SPIRIT	PRISMA-P
Clinical practice guidelines	AGREE	RIGHT

Translations

Some reporting guidelines are also available in languages other than English. Find out more in our Translations section.

We have also translated some of our website pages into other languages:
EQUATOR resources in Spanish

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry
	2b	All items from the World Health Organization Trial Registration Data Set
Protocol version	3	Date and version identifier
Funding	4	Sources and types of financial, material, and other support
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors
	5b	Name and contact information for the trial sponsor
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)
Introduction		
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention
	6b	Explanation for choice of comparators
Objectives	7	Specific objectives or hypotheses
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)
Methods: Participants, interventions, and outcomes		
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size
Methods: Assignment of interventions (for controlled trials)		
Allocation:		
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions

SPIRIT (2)

Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial
Methods: Data collection, management, and analysis		
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)
Methods: Monitoring		
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor
Ethics and dissemination		
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions
	31b	Authorship eligibility guidelines and any intended use of professional writers
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code

SPIRIT (3)

Appendices

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated.

MAIN PUBLICATIONS

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. *Ann Intern Med* 2013;158:200-207.

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Overview

SPIRIT checklist

- [1-5] **Administrative information**
- [6-8] **Introduction**
- [9-15] **Methods: Participants, interventions, outcomes**
  - 9: Study setting
  - 10: Eligibility criteria
  - 11: Interventions
  - 12: Outcomes
  - 13: Participant timeline
  - 14: Sample size
  - **15: Recruitment**
- [16-17] **Methods: Assignment of interventions (for controlled trials)**
- [18-20] **Methods: Data collection, management, analysis**
- [21-23] **Methods: Monitoring**
- [24-31] **Ethics and dissemination**
- [32-33] **Appendices**

Recruitment

Item 15: Strategies for achieving adequate participant enrolment to reach target sample size.

Example

"Each center will screen subjects to achieve screening percentages of 50% women and 33% minority; screening will continue until the target population is achieved (12 subjects/site). We recognize that, because of exclusion by genotype and genotypic variation among diverse populations [Reference X], the enrolled cohort may not reflect the screened population. The enrollment period will extend over 12 months.

Recruitment Strategy:

Each clinical center involved in the ACRN [*Asthma Clinical Research Network*] was chosen based on documentation for patient availability, among other things. It is, however, worthy to note the specific plans of each center.

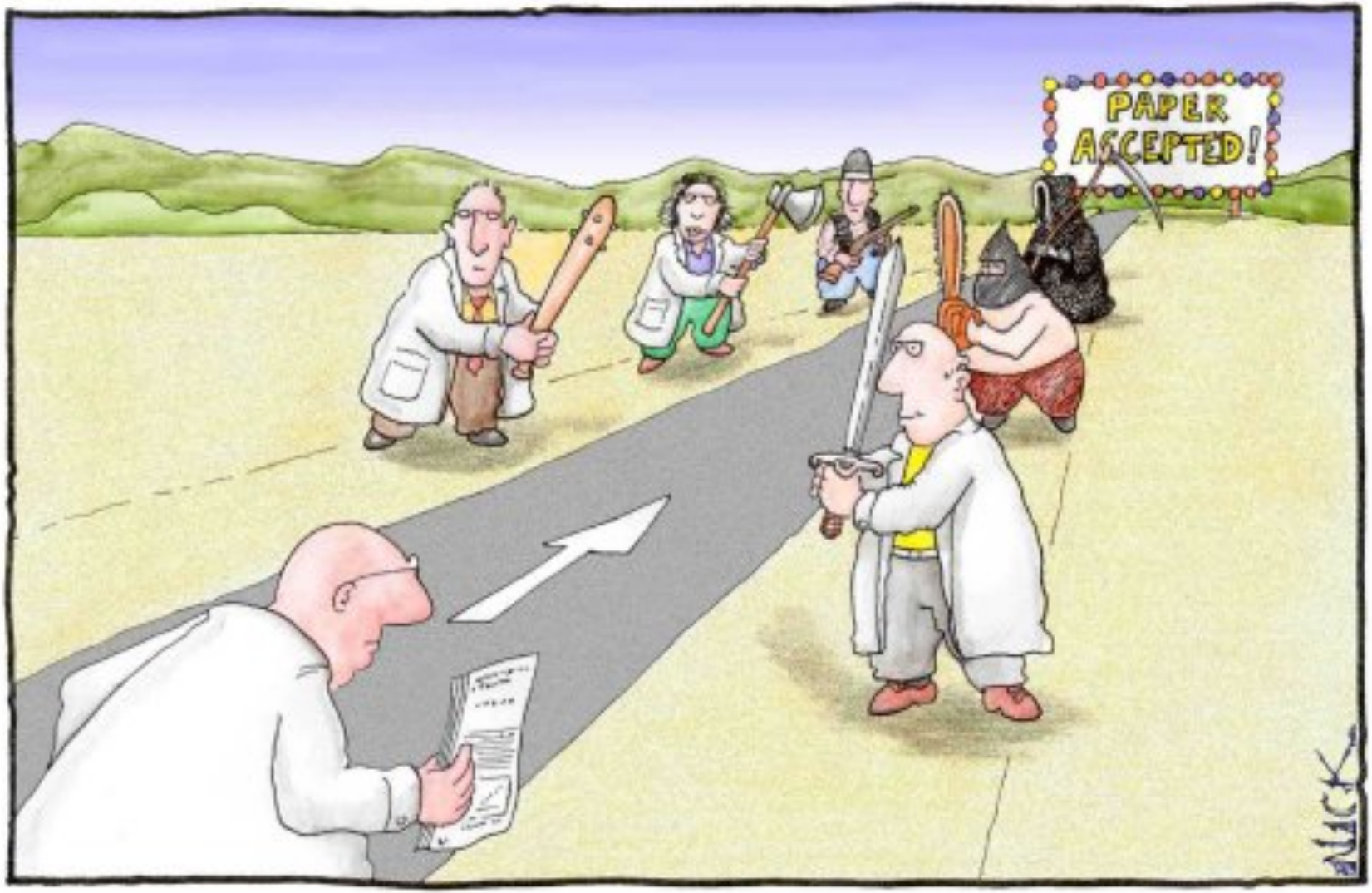
Harvard Clinical Center/Boston

. . . The Asthma Clinical Research Center at the Brigham & Women's Hospital utilizes three primary resources for identifying and recruiting potential subjects as described

SPIRIT Checklist

Publications & Downloads

SEPTRE (SPIRIT Electronic Protocol Tool & Resource)


PAPER ACCEPTED!

Publikation eines Studienprotokolls im Open Access Journal “Trials”

Trials

STUDY PROTOCOL Open Access

Effectiveness and cost-effectiveness of outpatient physiotherapy after knee replacement for osteoarthritis: study protocol for a randomised controlled trial

Vikki Wylde[1*], Neil Artz[2], Elsa Marques[1,3], Erik Lenguerrand[1], Samantha Dixon[1], Andrew D. Beswick[1], Amanda Burston[1], James Murray[4], Tarique Parwez[5], Ashley W. Blom[1] and Rachael Gooberman-Hill[1]

Abstract

Background: Primary total knee replacement is a common operation that is performed to provide pain relief and restore functional ability. Inpatient physiotherapy is routinely provided after surgery to enhance recovery prior to hospital discharge. However, international variation exists in the provision of outpatient physiotherapy after hospital discharge. While evidence indicates that outpatient physiotherapy can improve short-term function, the longer term benefits are unknown. The aim of this randomised controlled trial is to evaluate the long-term clinical effectiveness and cost-effectiveness of a 6-week group-based outpatient physiotherapy intervention following knee replacement.

Methods/design: Two hundred and fifty-six patients waiting for knee replacement because of osteoarthritis will be recruited from two orthopaedic centres. Participants randomised to the usual-care group ($n = 128$) will be given a booklet about exercise and referred for physiotherapy if deemed appropriate by the clinical care team. The intervention group ($n = 128$) will receive the same usual care and additionally be invited to attend a group-based outpatient physiotherapy class starting 6 weeks after surgery. The 1-hour class will be run on a weekly basis over 6 weeks and will involve task-orientated and individualised exercises.

The primary outcome will be the Lower Extremity Functional Scale at 12 months post-operative. Secondary outcomes include: quality of life, knee pain and function, depression, anxiety and satisfaction. Data collection will be by questionnaire prior to surgery and 3, 6 and 12 months after surgery and will include a resource-use questionnaire to enable a trial-based economic evaluation. Trial participation and satisfaction with the classes will be evaluated

Studienprotokoll-vorlagen von swissethics

Clinical Protocol template for Investigator initiated trials (IIT):

General information and instructions

This document is the Clinical Protocol template for IIT (Investigator initiated Trials) studies. swissethics strongly recommends using this template to develop clinical research protocols for trials testing an investigational medicinal product (IMP) or a medical device (MD) to be submitted to Swiss authorities.

This template is suitable for studies:

- involving IIT,
- performed in Switzerland, respectively where the Sponsor-Investigator is located in Switzerland
- where the study question does relate to the use of drug(s) or medical device effect(s),
- where the Swiss law on therapeutic products (HMG/LPTh and Federal Act on Medicinal Products and Medical Devices) applies,
- where the Swiss law on human research (Federal Act on Research involving Human Beings (HRA)) and its applicable ordinance ClinO/KlinV/OClin/OSRUm applies,
- that are interventional*

*health related interventional studies include research in preventive, diagnostic, therapeutic, palliative or rehabilitation activities that are examined in the context of a clinical trial.

The current template is based on:

- AGEK – CT CER / Swissmedic guidelines: "Studienprotokolle von klinischen, Investigator-initiated' Studien/Versuchen / Exigences des protocoles d'études/d'essais cliniques initiés par l'investigateur" dated 24.02.2009,
- the Federal Act on Research involving Human Beings (HRA) and its applicable ordinance (ClinO e/KlinV d/OClin f/OSRUm i)
- the SPIRIT statement and
- ICH-GCP E6, section 6
- EN ISO14155:2011: Annex A
- Swiss clinical trials portal (http://www.kofam.ch/en/swiss-clinical-trials-portal.html)

This template attempts to provide a general format applicable to all clinical trials evaluating an investigational product (drugs or medical devices).

Note that *instructions* are indicated in *blue italics* and they need be deleted (or alternatively may be formatted as "hidden Text" that will not show in printing).

Section headings and template text formatted in **regular type red** gives you reference to the legal requirements. This text may be deleted.

Section headings and template text formatted in regular type (black) should be included in your protocol document as provided in the template.

Header and footer should contain the following information (on all pages): [Protocol Title], [Page x of xx], [version x, DD/MM/YYYY], [Study ID]

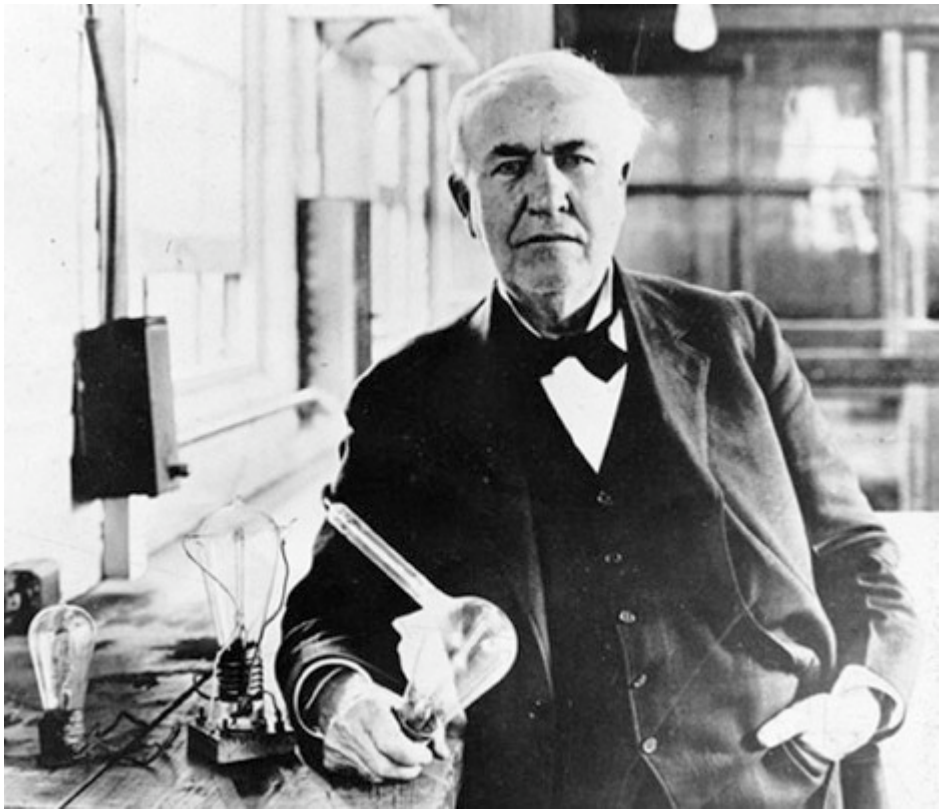
In places where the information is redundant, it is acceptable to reference another section, to document or to state its redundancy but the section has not to be deleted.

Refer questions regarding use of this protocol template to swissethics, info@swissethics.ch, phone: +41 31 306 93 95, www.swissethics.ch.

Sollen nur Erfolgsgeschichten erzählt werden?

” Young man, why would I feel like a failure? And why would I ever give up?
I now know definitively over 2,000 ways that an electric light bulb will **not** work.
Success is almost in my grasp.“

Thomas Edison



“Take Home Messages”

- Studienqualität & Berichtsqualität hängen zusammen, aber sind nicht das Gleiche
- Wertvolle method. Information findet sich oft in Protokollen, aber später nicht mehr im Manuskript
- Zeitlicher Mehraufwand im Protokollstadium (inkl. Publikation) zahlt sich aus
- SPIRIT & andere Reporting Guidelines helfen, über Forschung transparent und vollständig zu berichten
- EQUATOR Network bietet frei zugängliche Online-Bibliothek
- Publikation trägt zu Transparenz & Vermeidung von “Research Waste” bei

Cochrane Rehabilitation at the Global Evidence Summit

The Global Evidence Summit 2017 was a unique event. It was the first time that Cochrane, the Campbell Collaboration, the Guidelines International Network, the International Society for Evidence-based Health Care, and the Joanna Briggs Institute joined together to create this premiere event in evidence-based policy.

You can read the highlights from The Global Evidence Summit in a Cochrane.org news piece.

The central message of the Summit was that evidence needs to be properly communicated to ensure that it is part of the decision making process and not ignored, as so often happens. **Stefano Negrini** commented: "It was really interesting to see how many people in the different fields are working together to develop evidence to be offered to politicians and the general public, in order to allow them to make proper decisions. There was a unanimous agreement that diffusing the evidence in whatever field is important for all the scientists. Consequently, the understanding of the means with which we have to bring messages to the different audiences becomes of paramount importance. Media and their way of communicating, but also politicians and their need for synthesis, and the public who are sensitive to stories and not to long talks and dry data, were all aspects discussed during the conference."

The merging of the different organisations broadened the views and brought together an incredible panel of leaders and scientists with a global vision of bringing evidence to the post-truth world. The programme was full of plenaries, working meetings, hands-on workshops, and orals and posters presentations.

"It was interesting to see how Evidence Based Medicine is not isolated and there is a real global movement supporting the use of and struggling for Evidence in different fields: researchers are not alone. This is very relevant for Cochrane Rehabilitation where RCTs are not always the best way to produce evidence", said Carlotte Kiekens.

Six members of Cochrane Rehabilitation attended the meeting: the Director **Stefano Negrini**, the Coordinator **Carlotte Kiekens**, the Review Database Committee Chair **William Levack**, the Methodology Committee Co-Chair **Thorsten Meyer**, the Rehabilitation Professional Representative **Tracey Howe** and a PhD Student that is part of the Headquarters Staff Chiara Arienti.