

# Lack of transparent reporting of trial monitoring approaches in randomised controlled trials: A systematic review of contemporary protocol papers

Shao-Fan Hsieh<sup>1,2</sup> , Victoria Yorke-Edwards<sup>1</sup> , Macey L Murray<sup>1,3,4</sup> ,  
Carlos Diaz-Montana<sup>1</sup> , Sharon B Love<sup>1\*</sup>  and Matthew R Sydes<sup>1,5\*</sup> 

Clinical Trials  
1–12  
© The Author(s) 2023



Article reuse guidelines:  
sagepub.com/journals-permissions  
DOI: 10.1177/17407745231143449  
journals.sagepub.com/home/ctj



## Abstract

**Background:** Monitoring is essential to ensure patient safety and data integrity in clinical trials as per Good Clinical Practice. The Standard Protocol Items: Recommendations for Interventional Trials Statement and its checklist guides authors to include monitoring in their protocols. We investigated how well monitoring was reported in published ‘protocol papers’ for contemporary randomised controlled trials.

**Methods:** A systematic search was conducted in PubMed to identify eligible protocol papers published in selected journals between 1 January 2020 and 31 May 2020. Protocol papers were classified by whether they reported monitoring and, if so, by the details of monitoring. Data were summarised descriptively.

**Results:** Of 811 protocol papers for randomised controlled trials, 386 (48%; 95% CI: 44%–51%) explicitly reported some monitoring information. Of these, 20% (77/386) reported monitoring information consistent with an on-site monitoring approach, and 39% (152/386) with central monitoring, 26% (101/386) with a mixed approach, while 14% (54/386) did not provide sufficient information to specify an approach. Only 8% (30/386) of randomised controlled trials reported complete details about all of scope, frequency and organisation of monitoring; frequency of monitoring was the least reported. However, 6% (25/386) of papers used the term ‘audit’ to describe ‘monitoring’.

**Discussion:** Monitoring information was reported in only approximately half of the protocol papers. Suboptimal reporting of monitoring hinders the clinical community from having the full information on which to judge the validity of a trial and jeopardises the value of protocol papers and the credibility of the trial itself. Greater efforts are needed to promote the transparent reporting of monitoring to journal editors and authors.

## Keywords

Systematic review, trial monitoring, on-site monitoring, central monitoring, risk-based monitoring, reporting monitoring, protocol paper, randomised controlled trial

## Background

Clinical trial monitoring<sup>1</sup> plays a vital role in ensuring participants’ well-being is protected, trial data are accurate and complete, and the conduct of the trial complies with the protocol, regulatory requirements and Good Clinical Practice (GCP) guidelines.<sup>2</sup> ‘Monitoring’ here refers to the methods used by a sponsor to oversee the conduct of, and reporting of data from, clinical trials, including the ‘review of site processes, procedures and records, and verification of the accuracy of data submitted to the sponsor’.<sup>3</sup> In the past, clinical trials predominantly relied on on-site monitoring, in which trial monitors systematically and repeatedly visited sites

<sup>1</sup>MRC Clinical Trials Unit at UCL, Institute of Clinical Trials and Methodology, University College London, London, UK

<sup>2</sup>Division of Medicine, University College London, London, UK

<sup>3</sup>Health Data Research UK, London, UK

<sup>4</sup>NHS Digital, NHS Digital, Data Services Directorate, NHS Digital, London, UK

<sup>5</sup>British Heart Foundation Data Science Centre, Health Data Research UK, London, UK

\*These authors contributed equally.

## Corresponding author:

Victoria Yorke-Edwards, MRC Clinical Trials Unit at UCL, Institute of Clinical Trials and Methodology, University College London, 90 High Holborn, London WC1V 6LJ, UK.  
Email: v.yorke-edwards@ucl.ac.uk

# Methods Trial Papers

**K.A. Kuhn, J.R. Warren, T.-Y. Leong**



## Methods Trial Papers:

, *Papers on Sociological Methods* Francis Stuart Chapin, 1924 *The Advanced Handbook of Methods in Evidence Based Healthcare* Andrew Stevens, Keith Abrams, John Brazier, Ray Fitzpatrick, Richard Lilford, 2001-01-02 This handbook is an excellent reflection of the growing maturity and methodological sophistication of the field of Health Technology Assessment The Handbook covers a spectrum of issues from primary evidence clinical trials through reviews and meta analysis to identifying and filling gaps in the evidence Up to date clearly written and well edited the handbook is a needed addition to any personal or professional library dealing with Health Technology Assessment Professor David Banta TNO Prevention and Health The Netherlands This text presents the most advanced knowledge on methodology in health care research and will form the backbone of many future studies Paula Roberts Nurse Researcher The effectiveness revolution both in research and clinical practice has tested available methods for health services research to the extreme How far can observational methods routine data and qualitative methods be used in health care evaluation What cost and outcome measures are appropriate and how should data be gathered With the support of over two million pounds from the British Health Technology Assessment Research Programme the research project for this Handbook has led to both a synthesis of all of the existing knowledge in these areas and an agenda for future debate and research The chapters and their authors have been selected through a careful process of peer review and provide a coherent and complete approach to the field The handbook has been a unique collaboration between internationally regarded clinicians statisticians epidemiologists social scientists health economists and ethicists It provides the most advanced thinking and the most authoritative resource for a state of the art review of methods of evaluating health care and will be required reading for anyone involved in health services research and management

MEDINFO 2007 K.A. Kuhn, J.R. Warren, T.-Y. Leong, 2007-08-02 Contains papers which reflect the breadth and depth of the field of biomedical and health informatics covering topics such as health information systems education standards consumer health and human factors emerging technologies sustainability organizational and economic issues genomics and image and signal processing **Sessional Papers of the Dominion of Canada** Canada. Parliament, 1901 Report of the Dominion fishery commission on the fisheries of the province of Ontario 1893 issued as vol 26 no 7 supplement

**Parliamentary Papers** Great Britain. Parliament. House of Commons, 1903 **Paper**, 1916 *Text Mining of the Scientific Literature to Identify Pharmacogenomic Interactions* Yael Garten, 2010 Pharmacogenomics is the study of how variation in the human genome impacts drug response in patients It is a major driving force of personalized medicine in which drug choice and dosing decisions are informed by individual information such as DNA genotype The field of pharmacogenomics is in an era of explosive growth massive amounts of data are being collected and knowledge discovered which promises to push forward the reality of individualized clinical care However this large amount of data is dispersed in many journals in the scientific literature and pharmacogenomic findings are discussed in a variety of non standardized ways

It is thus challenging to identify important associations between drugs and molecular entities particularly genes and gene variants Thus these critical connections are not easily available to investigators or clinicians who wish to survey the state of knowledge for any particular gene drug disease or variant Manual efforts have attempted to catalog this information however the rapid expansion of pharmacogenomic literature has made this approach infeasible Natural Language Processing and text mining techniques allow us to convert free style text to a computable searchable format in which pharmacogenomic concepts such as genes drugs polymorphisms and diseases are identified and important links between these concepts are recorded My dissertation describes novel computational methods to extract and predict pharmacogenomic relationships from text In one project we extract pharmacogenomic relationships from the primary literature using text mining We process information at the fine grained sentence level using full text when available In a second project we investigate the use of these extracted relationships in place of manually curated relationships as input into an algorithm that predicts pharmacogenes for a drug of interest We show that for this application we can perform as well with text mined relationships as with manually curated information This approach holds great promise as it is cheaper faster and more scalable than manual curation Our method provides us with interesting drug gene relationship predictions that warrant further experimental investigation In the third project we describe knowledge inference in the context of pharmacogenomic relationships Using cutting edge natural language processing tools and automated reasoning we create a rich semantic network of 40 000 pharmacogenomic relationships distilled from 17 million Medline abstracts This network connects over 200 entity types with clear semantics using more than 70 unique types of relationships We use this network to create collections of precise and specific types of knowledge and infer relationships not stated explicitly in the text but rather inferred from the large number of related sentences found in the literature This is exciting because it demonstrates that we are able to overcome the heterogeneity of written language and infer the correct semantics of the relationship described by authors Finally we can use this network to identify conflicting facts described in the literature to study change in language use over time and to predict drug drug interactions These achievements provide us with new ways of interacting with the literature and the knowledge embedded within it and help ensure that we do not bury the knowledge embodied in the publications but rather connect the often fragmented and disconnected pieces of knowledge spread across millions of articles in hundreds of journals We are thereby brought one step closer to the realization of personalized medicine and ensure that as scientists we continue to build on the knowledge discovered by past generations and truly to stand on the shoulders of giants

**The Mixed Methods Research Workbook** Michael D. Fetters,2019-10-03 The Mixed Methods Research Workbook by Michael Fetters is the perfect tool for doctoral students and researchers who want support throughout their research project as well as a practical way to apply the knowledge they have learned With this text students can tackle their mixed methods research project with confidence

*Technical Association of the Pulp and Paper Industry* ,1974      **Sessional Papers** ,1903 Report of the Dominion fishery

commission on the fisheries of the province of Ontario 1893 issued as vol 26 no 7 supplement      Paper American Society of Mechanical Engineers,1916      **The Manuscripts of the House of Lords 1678[-1693] ...** Great Britain. Parliament. House of Lords,1887      **Transactions of the American Society of Civil Engineers** American Society of Civil Engineers,1929 Vols 29 30 contain papers of the International Engineering Congress Chicago 1893 v 54 pts A F papers of the International Engineering Congress St Louis 1904      **The Boy's Own Paper** ,1882      *Common-law Pleading ... Instruction Paper* American School (Lansing, Ill.),1923      The Photographic Journal of America ,1919      **Papers presented at the technical sessions held concurrently with the 1964 Systems Engineering Exposition, New York City, June 8-11, 1964** ,1964      **Pulp and Paper Magazine of Canada** ,1918      **Report of the Royal Commission on Historical Manuscripts** Great Britain. Royal Commission on Historical Manuscripts,1887 First to ninth reports 1870 1883 84 with appendices giving reports on unpublished manuscripts in private collections Appendices after v 15a pt 10 issued without general title

Ignite the flame of optimism with is motivational masterpiece, Fuel Your Spirit with **Methods Trial Papers** . In a downloadable PDF format ( \*), this ebook is a beacon of encouragement. Download now and let the words propel you towards a brighter, more motivated tomorrow.

<https://media.cfan.org/files/uploaded-files/Documents/epitome%20pms%20manual.pdf>

## **Table of Contents Methods Trial Papers**

1. Understanding the eBook Methods Trial Papers
  - The Rise of Digital Reading Methods Trial Papers
  - Advantages of eBooks Over Traditional Books
2. Identifying Methods Trial Papers
  - Exploring Different Genres
  - Considering Fiction vs. Non-Fiction
  - Determining Your Reading Goals
3. Choosing the Right eBook Platform
  - Popular eBook Platforms
  - Features to Look for in an Methods Trial Papers
  - User-Friendly Interface
4. Exploring eBook Recommendations from Methods Trial Papers
  - Personalized Recommendations
  - Methods Trial Papers User Reviews and Ratings
  - Methods Trial Papers and Bestseller Lists
5. Accessing Methods Trial Papers Free and Paid eBooks
  - Methods Trial Papers Public Domain eBooks
  - Methods Trial Papers eBook Subscription Services
  - Methods Trial Papers Budget-Friendly Options
6. Navigating Methods Trial Papers eBook Formats

- ePub, PDF, MOBI, and More
  - Methods Trial Papers Compatibility with Devices
  - Methods Trial Papers Enhanced eBook Features
7. Enhancing Your Reading Experience
    - Adjustable Fonts and Text Sizes of Methods Trial Papers
    - Highlighting and Note-Taking Methods Trial Papers
    - Interactive Elements Methods Trial Papers
  8. Staying Engaged with Methods Trial Papers
    - Joining Online Reading Communities
    - Participating in Virtual Book Clubs
    - Following Authors and Publishers Methods Trial Papers
  9. Balancing eBooks and Physical Books Methods Trial Papers
    - Benefits of a Digital Library
    - Creating a Diverse Reading Collection Methods Trial Papers
  10. Overcoming Reading Challenges
    - Dealing with Digital Eye Strain
    - Minimizing Distractions
    - Managing Screen Time
  11. Cultivating a Reading Routine Methods Trial Papers
    - Setting Reading Goals Methods Trial Papers
    - Carving Out Dedicated Reading Time
  12. Sourcing Reliable Information of Methods Trial Papers
    - Fact-Checking eBook Content of Methods Trial Papers
    - Distinguishing Credible Sources
  13. Promoting Lifelong Learning
    - Utilizing eBooks for Skill Development
    - Exploring Educational eBooks
  14. Embracing eBook Trends
    - Integration of Multimedia Elements
    - Interactive and Gamified eBooks

## Methods Trial Papers Introduction

Methods Trial Papers Offers over 60,000 free eBooks, including many classics that are in the public domain. Open Library: Provides access to over 1 million free eBooks, including classic literature and contemporary works. Methods Trial Papers Offers a vast collection of books, some of which are available for free as PDF downloads, particularly older books in the public domain. Methods Trial Papers : This website hosts a vast collection of scientific articles, books, and textbooks. While it operates in a legal gray area due to copyright issues, its a popular resource for finding various publications. Internet Archive for Methods Trial Papers : Has an extensive collection of digital content, including books, articles, videos, and more. It has a massive library of free downloadable books. Free-eBooks Methods Trial Papers Offers a diverse range of free eBooks across various genres. Methods Trial Papers Focuses mainly on educational books, textbooks, and business books. It offers free PDF downloads for educational purposes. Methods Trial Papers Provides a large selection of free eBooks in different genres, which are available for download in various formats, including PDF. Finding specific Methods Trial Papers, especially related to Methods Trial Papers, might be challenging as theyre often artistic creations rather than practical blueprints. However, you can explore the following steps to search for or create your own Online Searches: Look for websites, forums, or blogs dedicated to Methods Trial Papers, Sometimes enthusiasts share their designs or concepts in PDF format. Books and Magazines Some Methods Trial Papers books or magazines might include. Look for these in online stores or libraries. Remember that while Methods Trial Papers, sharing copyrighted material without permission is not legal. Always ensure youre either creating your own or obtaining them from legitimate sources that allow sharing and downloading. Library Check if your local library offers eBook lending services. Many libraries have digital catalogs where you can borrow Methods Trial Papers eBooks for free, including popular titles. Online Retailers: Websites like Amazon, Google Books, or Apple Books often sell eBooks. Sometimes, authors or publishers offer promotions or free periods for certain books. Authors Website Occasionally, authors provide excerpts or short stories for free on their websites. While this might not be the Methods Trial Papers full book , it can give you a taste of the authors writing style. Subscription Services Platforms like Kindle Unlimited or Scribd offer subscription-based access to a wide range of Methods Trial Papers eBooks, including some popular titles.

## FAQs About Methods Trial Papers Books

How do I know which eBook platform is the best for me? Finding the best eBook platform depends on your reading preferences and device compatibility. Research different platforms, read user reviews, and explore their features before making a choice. Are free eBooks of good quality? Yes, many reputable platforms offer high-quality free eBooks, including classics and public domain works. However, make sure to verify the source to ensure the eBook credibility. Can I read

eBooks without an eReader? Absolutely! Most eBook platforms offer web-based readers or mobile apps that allow you to read eBooks on your computer, tablet, or smartphone. How do I avoid digital eye strain while reading eBooks? To prevent digital eye strain, take regular breaks, adjust the font size and background color, and ensure proper lighting while reading eBooks. What the advantage of interactive eBooks? Interactive eBooks incorporate multimedia elements, quizzes, and activities, enhancing the reader engagement and providing a more immersive learning experience. Methods Trial Papers is one of the best book in our library for free trial. We provide copy of Methods Trial Papers in digital format, so the resources that you find are reliable. There are also many Ebooks of related with Methods Trial Papers. Where to download Methods Trial Papers online for free? Are you looking for Methods Trial Papers PDF? This is definitely going to save you time and cash in something you should think about.

### **Find Methods Trial Papers :**

[epitome pms manual](#)

**epson manual px710w**

**epson epl 5700 page printer service repair manual**

[epson 140reference guide](#)

[epson 590 service manual](#)

[envisions math 2 nd grade pretest](#)

**eoc review rc 5**

**epson printer maintenance reset tool**

**epson l300 manual**

**enyou dtv1500 atv1500 user guide**

[environmental science for ap answers](#)

[entrepreneuriat social innover au service de linteacuterecirt-geacuteneacuteral](#)

[epri instrumentation study guide](#)

[eoc coach answer keys english one](#)

**eog notification letter**

### **Methods Trial Papers :**

Self-Help Resources / Guardianship and Conservatorship Requirements of a Guardian or Conservator of a Minor · Reports

required from the conservator · Moving a conservatorship · Withdrawing funds in a restricted ... Guardianship of a Minor This page is for the appointment by the district court of an individual to serve as guardian of a minor child. Its primary focus is on procedures when ... Guardianship Guardianship is a legal process that allows someone (usually a family member) to ask the court to find that a person age 18 or older is unable (incompetent) ... Office of Public Guardian - Utah Aging and Adult Services The Office of Public Guardian (OPG) provides guardianship and conservatorship services for adults\* who are unable to make basic life decisions for ... Guardianship Associates of Utah We provide direct guardianship and conservator services, as well as trust management and executor services for Special Needs Trusts. We are also passionate in ... Guardianship & Conservatorship Dec 6, 2017 — A conservatorship and guardianship allows someone to act for someone else. They cannot be created without an order by a judge. Guardianships and Conservatorships in Utah In Utah, a guardian primarily has the court-appointed power to provide for the physical well-being of a protected person and a conservator is the court- ... Considering Guardianship Guardianship is a court process. The State of Utah allows for two types of guardianship. These include a plenary (full) or limited guardianship. A Plenary ... Information — Guardianship Associates of Utah Guardianship is surrogate decision making for a person who is over the age of 18 and is unable to make decisions due to some level of incapacity. How to Get Guardianship of a Child in Utah Traditional guardianship. The interested adult files a court petition directly with the help of Heber lawyers to the county district court where the minor lives ... Losing Control? Sovereignty in an Age of Globalization Immigration Tests the New Order. Economic globalization denationalizes national economies; in contrast, immigration is renationalizing politics. There is a ... Immigration Tests New Order By Sassen: A Comparative ... The book targets a specialized audience with previous knowledge and particular interest in the topic of the migration crisis. It was published in 1995 by ... Immigration tests the new order sassen - resp.app Mar 25, 2023 — Yeah, reviewing a book immigration tests the new order sassen could be credited with your close associates listings. This is just one of the ... Reading free Immigration tests the new order sassen ... Aug 14, 2023 — Yeah, reviewing a books immigration tests the new order sassen could accumulate your near links listings. This is just one of the solutions ... The Repositioning of Citizenship by S Sassen · 2003 · Cited by 183 — issue is that of the historicity and the embeddedness of both categories, citizenship and the national state, rather than their purely formal features. The Repositioning of Citizenship: Emergent Subjects and ... by S Sassen · 2002 · Cited by 400 — SASSEN: REPOSITIONING OF CITIZENSHIP 1 1 ethnicity, religion, sex, sexual ... instance, prior to the new immigration law passed in 1996 who could prove ... saskia sassen The new immigration is further characterized by the immigrants' tendency to cluster in a few key U.S. regions. This was true as well of earlier immigration ... Losing Control?: Sovereignty in an Age of Globalization Sassen argues that a profound transformation is taking place, a partial denationalizing of national territory seen in such agreements as NAFTA and the European ... 2 The de facto Transnationalizing of Immigration Policy Discussions cover the operation of states under a new rule of law, the two

cornerstones of immigration policy in developed countries — the border and individual ... Saskia Sassen by S Sassen · Cited by 159 — Next I briefly examine the question of immigrant remittances as one lens into the broader subject of the formation of alternative political economies and how ... ANSWER KEY - WORKBOOK 8.1. 1. 2 I was about to leave the office when the phone rang. 3 You weren't supposed to tell her the secret! 4 We were meant to pay in advance. 7A WORKBOOK ANSWERS 1 Three from: measuring heart beats, temperature, urine tests, blood tests. Accept other sensible responses. 2 The patient has spots. Answers © Pearson. 9. K c students' own answers, but should be backed up with a sensible reason. 4 Answers may vary. Some possible answers are: a explaining ... Pearson Education - solutions and answers Browse through your textbook and get expert solutions, hints, and answers to all exercises. ... Share worksheets, collaborate, and reach out to find other ... Answers 2 Students' own ideas about how we can tell that a life process is occurring in a certain item/organism. 3 The life process that can never be said to occur in. Answers 8Aa Nutrients. Student Book. 1: 8Aa Food and advertising. 1 Students' own answers: e.g. for energy, growth and repair, and health. Answer Key Worksheet 1 Worksheet 2 Worksheet 3 ... Jan 3, 2015 — Answer Key Worksheet 1 Worksheet 2 Worksheet 3 Worksheet 4. Answer Key ... Copyright © Pearson Education, Inc. Permission granted to reproduce ... 8A WORKBOOK ANSWERS 1 Students' own answers, making reference to the need for food for energy and/or growth, repairing the body, health. Some students may list specific ... Pearson Education Science Lesson Plans & Worksheets Find pearson education science lesson plans and teaching resources. Quickly find that inspire student learning.