The King's Centre for Integrative Chinese Medicine

INTEGRATING WISDOM, CATALYSING INNOVATION



KING'S College LONDON

KING'S HEALTH PARTNERS

The King's Centre for Integrative Chinese Medicine

Integrating Wisdom | Catalysing Innovation

https://www.kingscicm.org/

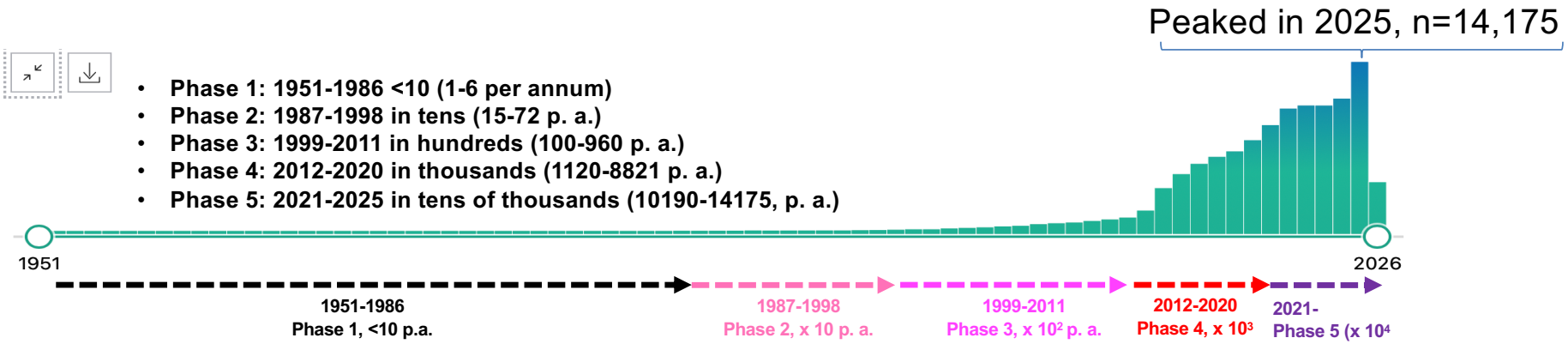
International Standards and Good Practice Guidelines:
Essential Instruments for Advancing Integrative Medicine

国际标准与规范：推动整合医学发展的核心工具

Qihe Xu, MD, PhD
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King's College London
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Integrative Medicine: gaining popularity in the past two decades

Pubmed search “integrative-medicine”, 100,745 hits up to 18 March 26



Is this a new era just begun?

Or is it an unsustainable campaign?

It depends,… on what to integrate and how



滥竽充数？



琴瑟和鸣！

Integrative Medicine (IM)

The definition by the WHO

The April 2024 Draft WHO traditional medicine strategy (2025-2034) for consultation:

Integrative Medicine is:

- an interdisciplinary and *evidence-informed* approach
- aimed at achieving whole-person health and well-being
- by using a *respectful* combination or fusion of biomedical and traditional and/or complementary medical knowledge, skills and practices.

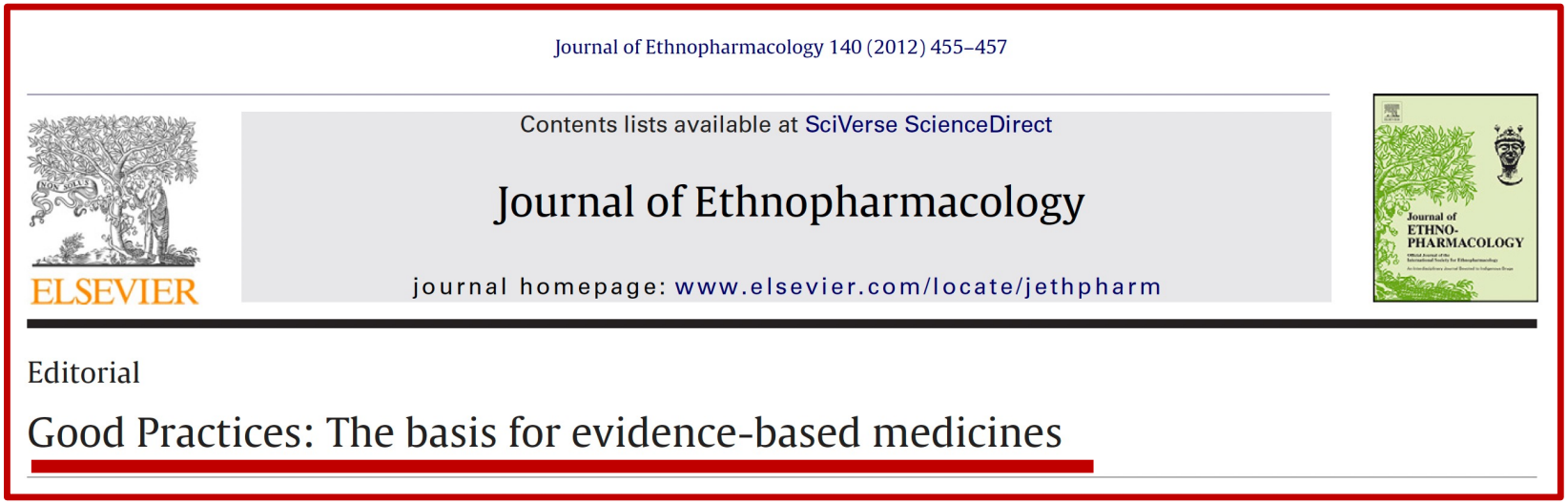
❑"respectful" was removed; "*evidence-informed* " was replaced by "evidence-based" in the final version adopted by the World Health Assembly in May 2025.

- *Respectful* could be **subjective**. However, for a sustainable future, it is essential for IM.

- This essentially means that any *integration* and *fusion* in integrative medicine must follow **objective** good practice standards and guidelines.

- Indeed, "evidence-based " is the right term, as it both emphasises **evidence** and upholds **good practices**.

Prof. Rob Verpoorte's editorial for the *GP-TCM Special Issue*, *Journal of Ethnopharmacology*, co-edited by Xu Q and Bauer R.



Journal of Ethnopharmacology 140 (2012) 455–457

Contents lists available at SciVerse ScienceDirect

Journal of Ethnopharmacology

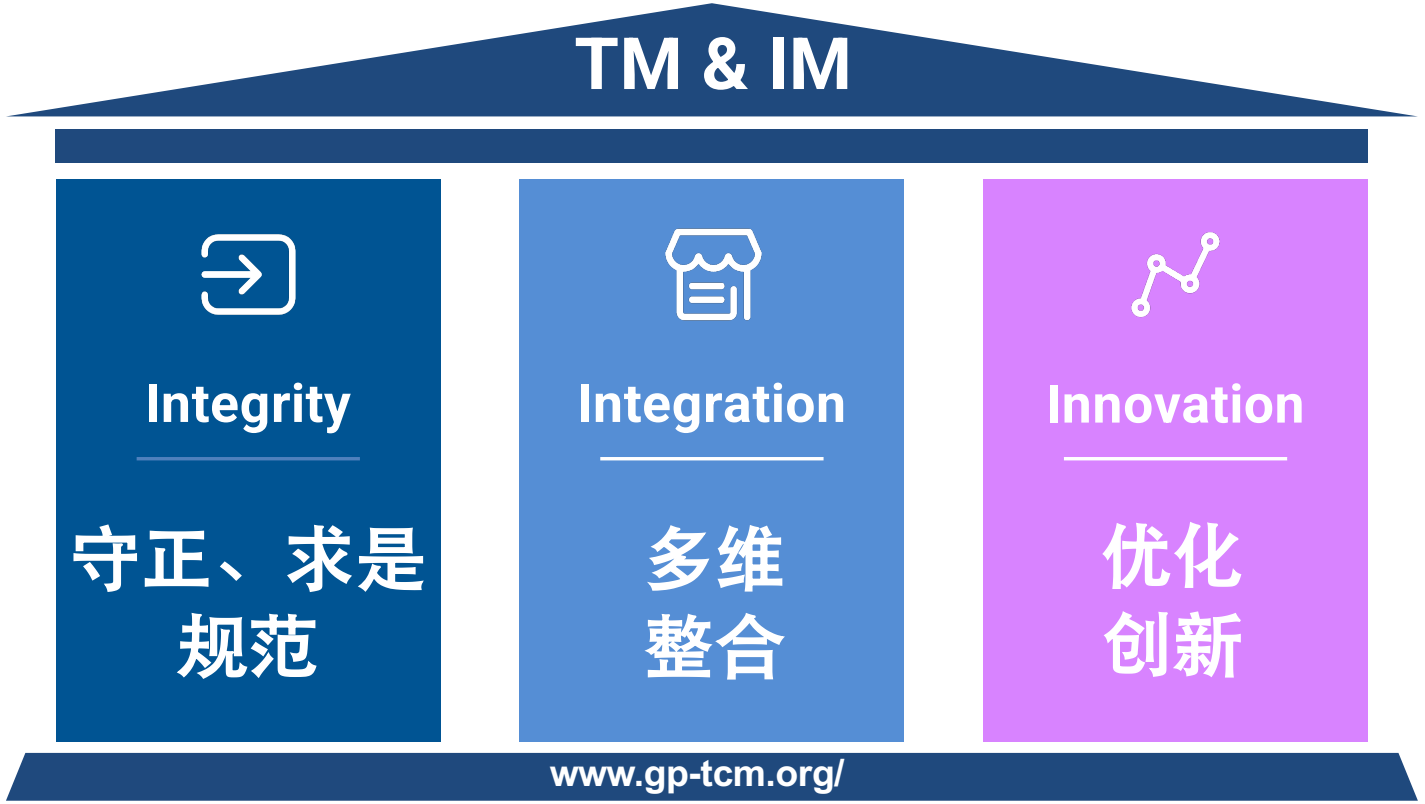
journal homepage: www.elsevier.com/locate/jethpharm

ELSEVIER

Editorial

Good Practices: The basis for evidence-based medicines

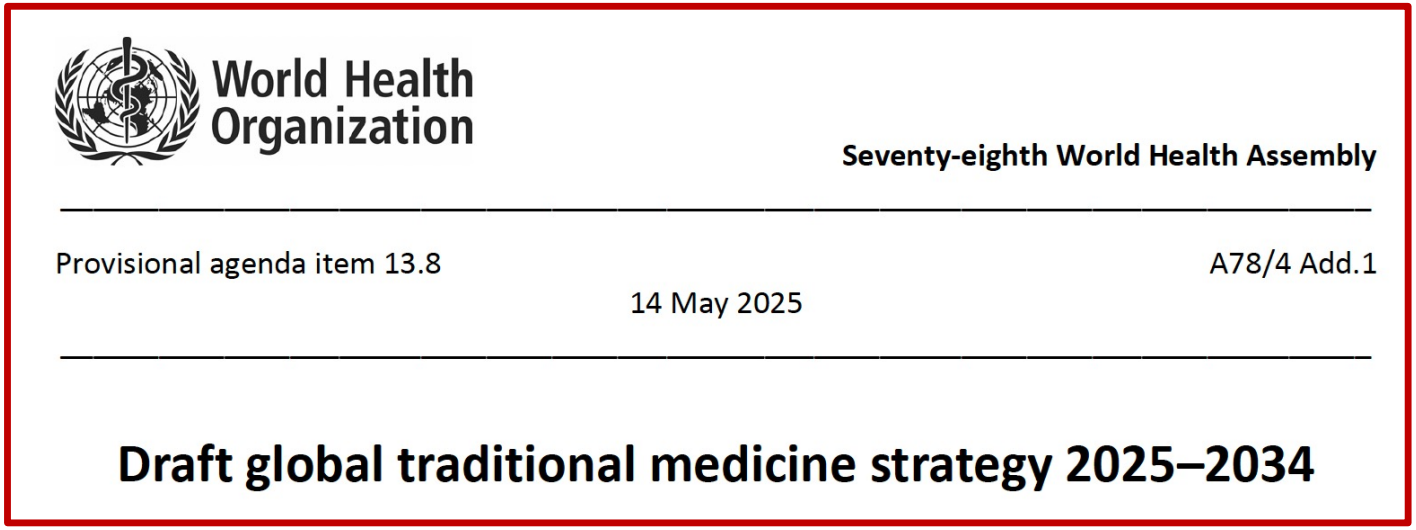
GP-TCM RA regards **integration** a central strategy for **innovation** and emphasises that **integration** must be built on **integrity** (good practice).



The quest for modernisation of traditional Chinese medicine.
Xu Q, *et al.* *BMC Complement Altern Med* **2013;13:**132 (>270 citations)

New WHO Traditional Medicine Strategy—Four Objectives

1. Building evidence base;
2. Creating appropriate regulatory mechanisms;
3. Integrating safe & effective TCIM into health systems;
4. Optimising the cross-sector value of TCIM and empowering communities.



World Health Organization

Seventy-eighth World Health Assembly

Provisional agenda item 13.8 A78/4 Add.1

14 May 2025

Draft global traditional medicine strategy 2025–2034

Talha Burki. *Lancet.* May 31, 2025; 405:1897-8

- The WHO strategy **repeatedly highlights the importance of research**.
- "We now have this **amazing opportunity** to contribute to the development of TM using **frontier scientific methods**".

  - AI, maturing omics technologies, systems biology & pharmacology, innovative RCTs, real-world research and implementation science;
  - Significant progress has been made in developing international standards (IS) and international good practice guidelines (IGPG).

GP-TCM defines good practice as striving for consensus while respecting differences

- It is compliance with commonly accepted guidelines in biomedical R&D and health sciences, including general guidelines for scientists (EQUATOR), journals (COPE) and regulators (ICH)

⇒

- GCCP2.0 (cell study)
- PREPARE, & ARRIVE2.0 (animal study)
- CONSORT (RCT)
- PRISMA (systemic review)
- MIQE (PCR)
- SAGER (Sex and Gender); and
- GATHER (Accurate and Transparent Health Estimates Reporting)……

- It also means **good practice guidelines** and **standards** particularly important for traditional, complementary and integrative medicine (TCIM)

⇒ **Main topic of this talk**

- EQUATOR: Enhancing QUAlity and Transparency Of health Research. https://www.equator-network.org
- COPE: The Committee on Publication Ethics guidelines: https://publicationethics.org
- ICH: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use: https://www.ich.org

Uzuner H, et al. Traditional Chinese medicine research in the post-genomic era: Good practice, priorities, challenges and opportunities. J Ethnopharmacol. 2012;140:458-68 (>100 citations)

TCIM-specific good practice guidelines & standards
求同尊异、和而不同的传统医药技术标准与指南

Standards & GxP guidelines

标准与指南

More internationally harmonised

国际同化度较高的标准与规范

具有国际影响力的区域性标准与规范

Regional guidelines with international importance

A scoping review of IS/IGPG by 20 authors from 11 countries & regions

范围综述： 11个国家的20位专家汇总了TCIM相关国际标准与国际规范



Prof. Xuanbin Wang
Hubei Medical University



Prof. Rudolf Bauer
University of Graz



Prof. Pierre Duez
University of Mons



Dr Qihe Xu
King's College London



Prof. Michael Heinrich
EIC, *Front Pharmacol*



Prof. Thomas Efferth
EIC, *PhytoMedicine*

frontiers | Frontiers in Pharmacology

TYPE Policy and Practice Reviews
PUBLISHED 09 April 2026
DOI 10.3389/fphar.2026.1742400

Frontiers in Pharmacology 9 April 2026;17:1742400.

Check for updates

OPEN ACCESS

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International standards and good practice guidelines in traditional, complementary and integrative medicine: a scoping review

Xuanbin Wang[1]*, Hongliang Li[1], Shun Jiang[1], Nian Yang[2], Dongpeng Wang[1], Hongxi Xu[3], Nicola Robinson [4,5], Lie-Fen Shyur[6], Michael Heinrich[7,8], Mei Wang [9], Monique S. J. Simmonds[10], Linda Zhong[11,12], Fatiha Brahmi[13], Thomas Efferth[14], Salvius Amuri Bakari[15], Clara Bik-San Lau[16], Wendy Wong[17], Rudolf Bauer[18]*, Pierre Duez[19]* and Qihe Xu[20,21]*

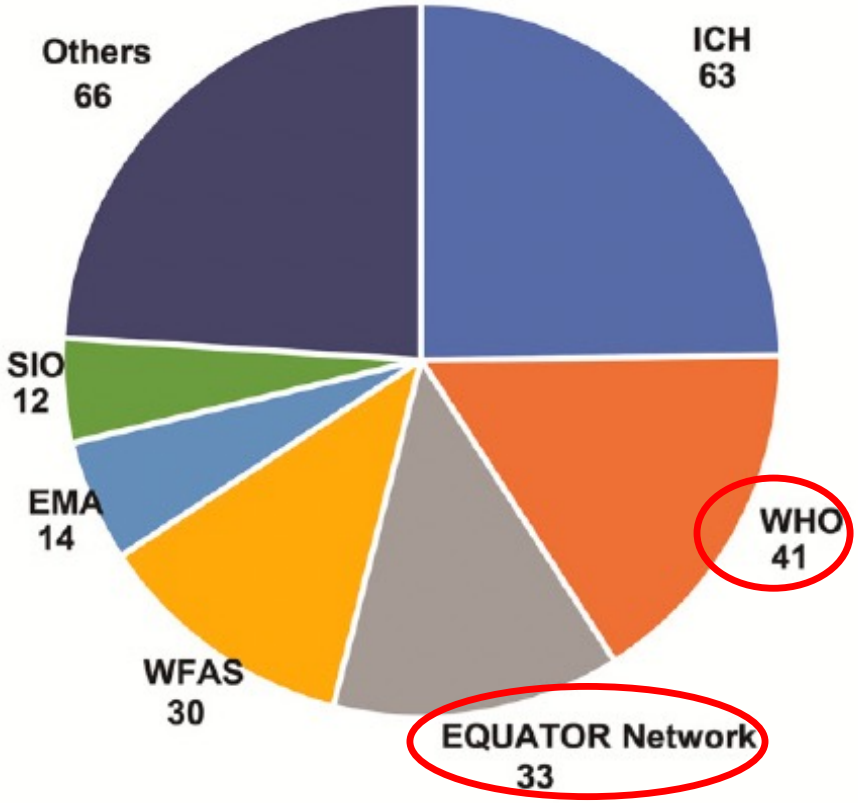
[1]Laboratory of Chinese Herbal Pharmacology, Department of Pharmacy, Renmin Hospital, Institute of Biomedicine Research, Hubei Key Laboratory of Wudang Local Chinese Medicine Research, Hubei University of Medicine, Shiyan, China, [2]The First Affiliated Hospital (Shenzhen People's Hospital), Southern University of Science and Technology, Shenzhen, China, [3]School of Pharmacy, Shanghai University of Traditional Chinese Medicine, Shanghai, China, [4]London South Bank University, London, United Kingdom, [5]Centre of Evidence Based Medicine, Beijing University of Chinese Medicine, Beijing,

Main findings

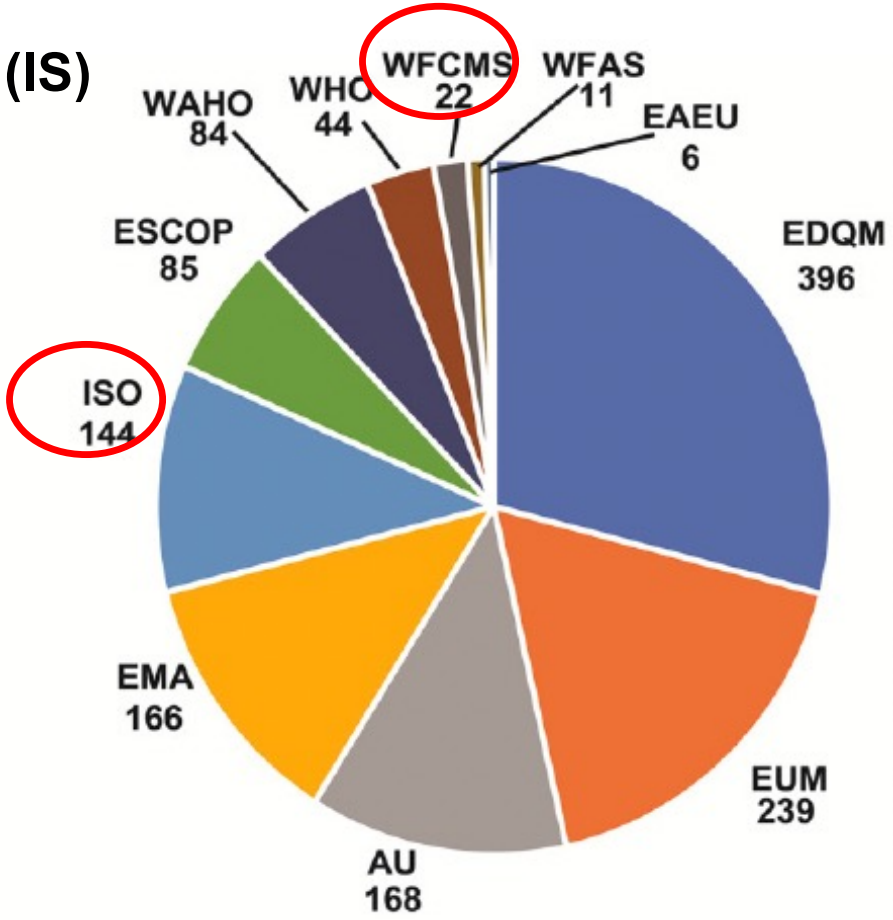
- **1624 TCIM-relevant IS/IGPG documents** and 402 related secondary documents are included for analysis.
- These IS/IGPG were produced by **33 international organisations and consortia.**

Publishers of IS/IGPG

A **(IGPG:** international guidelines)



B **(IS)**



Publishers of TCIM IS and IGPGs: Key Examples

发布TCIM国际标准与规范的组织：举例说明

- International Standardization Organization (ISO)
  国际标准化组织
- World Federation of Chinese Medicine Societies (WFCMS)
  世中联
- World Health Organization (WHO)
  世卫组织
- International consortia (EQUATOR, GP-TCM, etc)
  国际协作组织

ISO/TC 249

中医药技术委员会 → 传统医药技术委员会

- 2009- ISO/TC 249 first standards
- 1st May 2025, ISO/249 was renamed “Traditional Medicine Technical Committee”
- By 2nd Dec. 2025, ISO has published
  - 125 standards on **quality, safety and processing procedures of TCM raw materials & products**; and
  - 68 standards are being drafted.



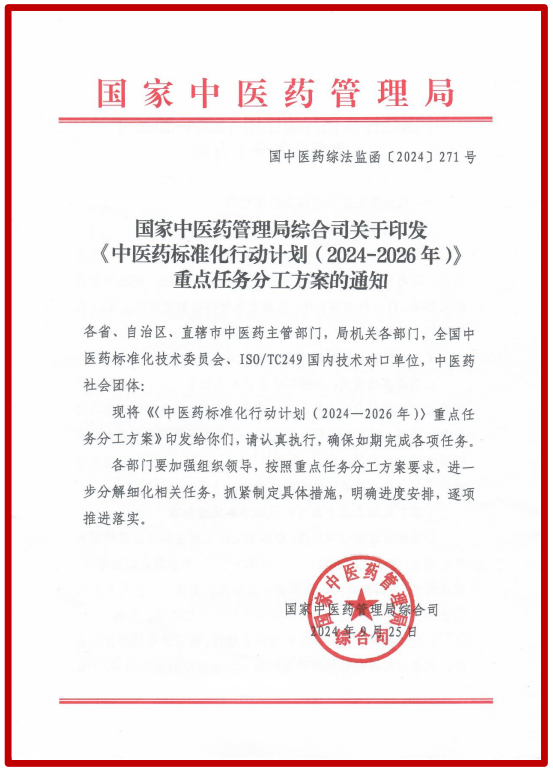
Prof. Yuandong Shen
Chair, ISO/TC 249
Shanghai University of TCM

- 2009： ISO/TC 249开始工作
- 2025年5月1日，ISO/TC 249更名为传统医药技术委员会
- 2025年12月2日， ISO/TC 249
  - 发布了125个中医药原材料和生产成品质量、安全性和加工程序的国际标准。
  - 68个国际标准正在制定中

Find updated information here:
https://www.iso.org/committee/598435.html

ISO is a partner preferred by the Chinese government in promoting TCM international standardisation

中医药标准国际化是中国政府推动的重点工作之一，ISO是官方推荐对接的国际平台



国 家 中 医 药 管 理 局

国中医药综法监函〔2024〕271 号

国家中医药管理局综合司关于印发
《中医药标准化行动计划（2024-2026 年）》
重点任务分工方案的通知

各省、自治区、直辖市中医药主管部门，局机关各部门，全国中医药标准化技术委员会、ISO/TC249 国内技术对口单位，中医药社会团体：

现将《《中医药标准化行动计划（2024—2026 年）》重点任务分工方案》印发给你们，请认真执行，确保如期完成各项任务。

各部门要加强组织领导，按照重点任务分工方案要求，进一步分解细化相关任务，抓紧制定具体措施，明确进度安排，逐项推进落实。

国家中医药管理局综合司
2024 年 4 月 25 日

一、优化中医药标准体系总体布局

二、加强重点领域标准供给

三、推动中医药标准与科技创新互动发展

四、推进中医药标准国际化

五、深化中医药标准改革创新

六、夯实中医药标准发展基础

七、保障措施

WFCMS partners with ISO and also publishes its own standards

世中联是ISO的主要伙伴，也独立发表的国际标准

http://www.wfcms.org/index.php/list/52.html

No	WFCMS 国际标准与指南 (n=22 by Nov. 2022))	发布时间
22	SCM 54-2020 中药处方要求 (TCM prescription)	2022-08-23
21	SCM 54-2020 中药调剂要求 (Dispensing)	2022-08-24
20	SCM 54-2020 中药给付要求 (Delivery)	2022-08-24
19	SCM 55-2020 中药煎服要求 (Decoction and taking)	2022-08-24
18	SCM-C 0039-2020 温控红外灸疗垫	2022-05-05
17	SCM-C 0014-2019 糖脂代谢病（瘅浊）中西医结合诊疗技术规范	2022-05-05
16	SCM-C 0011-2018 牛胶原肽粉	2022-05-05
15	SCM0051-2019 国际中医远程会诊服务规范	2022-05-05
14	SCM-C 0008-2017 耳穴探测仪	2022-04-28
13	SCM0050-2019 国际中医远程教育服务规范	2022-04-28
12	SCM0041-2014 世界中医药学科体系类目	2022-04-28
11	SCM0027-2019 凉茶饮料 (Liangcha herbal drinks)	2022-04-28
10	SCM0026-2019 浮针疗法技术操作规范	2022-04-28
9	SCM0024-2018 标准化煎药中心基本要求 (Standardised decoction-making centre)	2022-04-28
8	SCM0023-2019 热敏灸技术操作规范	2022-04-28
7	SCM0020-2017 中医药健康旅游服务要求	2022-04-28
6	SCM0018-2017 国际中医临床实践指南 糖尿病	2022-04-28
5	SCM0012-2014 国际中医医师测试与评审规范	2022-04-28
4	SCM0010-2012 世界中医学专业核心课程	2022-04-28
3	SCM0008-2011 国际中医医师专业技术职称分级标准	2022-04-28
2	SCM0004-2010 诊所设置与服务标准	2022-04-28
1	SCM0003-2009 世界中医学本科（CMD 前）教育标准	2022-04-28

Since then, WFCMS has published 6 more guidelines focusing on

- particular TCM drugs (Xuezhiping; Xinxuening) or diseases (CVD, CKD, intervertebral disc herniation, diabetes)



国际标准

当前位置： 首页 > 新闻信息 > 国际标准

SCM–TR 0009–2025 通络药物系统干预心血管事件链专家共识	2025–10–15
SCM 75–2024 国际中医技术操作规范 肠道灌洗技术治疗慢性肾脏病3b～5期	2025–10–15
SCM 84–2005 国际中医技术操作规范 中医整脊治疗腰椎间盘突出症	2025–06–30
SCM–TR 0007–2025 血脂平胶囊临床应用专家共识	2025–05–19
SCM–TR 0006–2025 心血宁片临床应用专家共识	2025–05–19
SCM18–2017 国际中医临床实践指南 糖尿病	2025–04–08

http://www.wfcms.org/index.php/list/52.html

WHO plays an indispensable role in international standardisation

世卫组织在发布、促进国际标准化与规范化中发挥着不可替代的作用

- WHO standards in acupuncture nomenclature and benchmark series on TM training & practice (2022): acupuncture, tuina, Ayurveda and Unani.

  世卫针灸术语，以及针灸、推拿、印度传统医学指南

Updates and future reporting - Traditional medecine
Report by the WHO Director-General. 75th WORLD HEALTH ASSEMBLY. 12 April 2022
https://apps.who.int/gb/ebwha/pdf_files/WHA75/A75_42-en.pdf

WHO Standards of TM terminologies and translation

世卫组织引领传统医学术语翻译的标准化

- WHO international standard terminologies on traditional medicine in the Western Pacific Region. 2007
- WHO international standard terminologies on traditional Chinese medicine (2022) and traditional Indian medicines (siddha, ayurveda, unani (2023)

WHO standardises TM diagnosis, bringing it in ICD-11

世卫组织标准化传统医学诊断，并将其带入国际疾病分类目录

- WHO. Chapter 26. Supplementary Chapter Traditional Medicine Conditions - Module I. ICD-11. International Classification of Diseases 11th Revision; The global standard for diagnostic health information. 1999; in effect, Jan. 2022.

https://www.who.int/teams/integrated-health-services/traditional-complementary-and-integrative-medicine

WHO guidelines on TM research & evaluation and herbal GMP was the foundation of the FP7 GP-TCM collaboration

世卫组织传统医药研究评估方法指南与草药生产规范

- WHO *General Guidelines* for Methodologies on Research and Evaluation of Traditional Medicine. 2000; p1-74 (>1000 citations)
- WHO Guidelines for Selecting Marker Substances of Herbal Origin for Quality Control of Herbal Medicines (2017)
- WHO Guidelines on Good Herbal Processing Practices for Herbal Medicines (2018)
- Guidelines on Good Manufacturing Practices for the Manufacture of Herbal Medicines (2018)
  - replacing the 2007 WHO Guidelines on GMP for Herbal Medicines.

https://www.who.int/teams/integrated-health-services/traditional-complementary-and-integrative-medicine (accessed 02/12/2025)

Good Practice in TCM Research in the Post-genomic Era (GP-TCM，2009-2012)

后基因组时代中医药研究的良好实践

- A €1m project funded by the European Commission, under its 7th Programme Framework
- 25 countries, 110 institutions & enterprises, >200 members
- Aimed at promoting EU-China collaboration in modernisation of TCM research



Uzuner H, et al. TCM research in the post-genomic era: good practice, priorities, challenges and opportunities. J Ethnopharmacol. 2012;140:458-68.



Prof. Kelvin Chan

University of Sydney



Prof. Pierre Duez

University of Mons



Prof. Monique Simmonds

Royal Botanic Gardens

Chan K, et al. **Good practice in reviewing and publishing studies on herbal medicine**, with special emphasis on traditional Chinese medicine and Chinese materia medica.

J Ethnopharmacol. 2012;140(3):469-75.

(247 citations)

World Flora Online - The WFO Plant List

https://wfoplantlist.org/plant-list

Best Practice in the chemical characterisation of extracts used in pharmacological and toxicological research: **The ConPhyMP Guidelines.** Heinrich M, et al. *Front Pharmacol.* 2022;13:953205.

药用植物鉴定、命名、提取、化学分析的指南

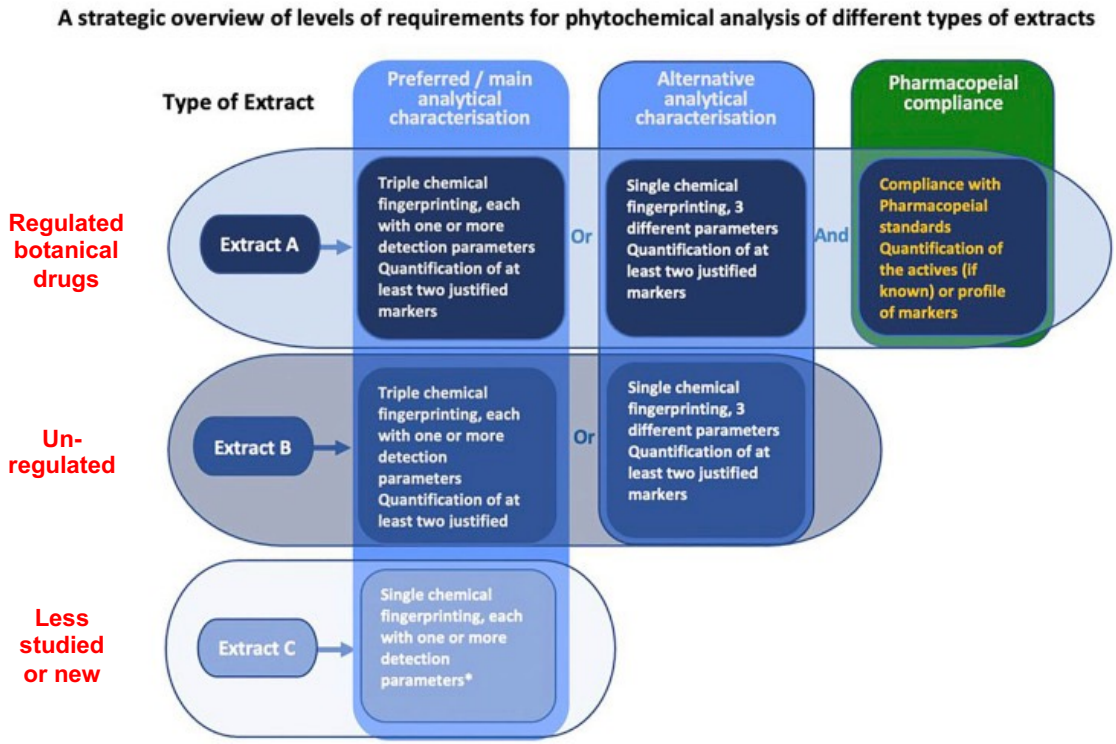


Prof. Michael Heinrich

University College London

ConPhyMP offers an online interactive tool for what is needed in the reporting pharmacology, toxicology and clinical effects of herbals:

https://ga-online.org/best-practice/





Prof. Zhaoxiang Bian
Former Chair, Clinical Studies Interest Group
GP-TCM RA

CONSORT Extension for Chinese Herbal Medicine Formulas 2017: Recommendations, Explanation, and Elaboration.
Cheng CW, et al; CONSORT-CHM Formulas 2017 Group.
Ann Intern Med. 2017;167(2):112-121.

(277 citations)

↑

Flower A, et al.
Guidelines for randomised controlled trials investigating Chinese herbal medicine.
J Ethnopharmacol. 2012;140(3):550-4.

(103 citations)

↑

Gagnier JJ, et al.
Reporting RCTs of Herbal Interventions: An Elaborated CONSORT Statement. Ann Intern Med. 2006;144(5):364-367.

(853 citations)



Prof. Hugh MacPherson
University of York

Revised STandards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA): extending the CONSORT statement.
MacPherson H, et al; STRICTA Revision Group.
Acupunct Med. 2010;28:83-93.

(1984 citations)

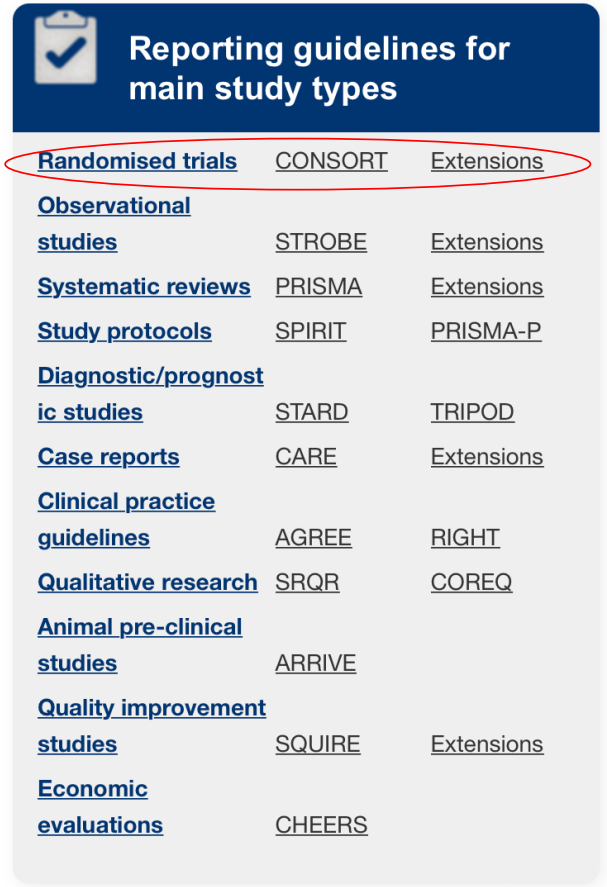
Standards for reporting interventions in controlled trials of acupuncture: the STRICTA recommendations.
MacPherson H, et al.
Complement Ther Med. 2001;9:246-9.

(280 citations)

695 minable & searchable guidelines, including 29 on TCIM
https://www.equator-network.org/reporting-guidelines/

CONSORT是Equator网络的一部分。后者发布**一系列指南**与**延伸指南**，旨在提升各种类型临床与实验研究的质量与透明度。

- **CONSORT is part of the Equator network**, which publishes **a series of guidelines** and extensions aimed at enhancing the quality and transparency of various types of health research.

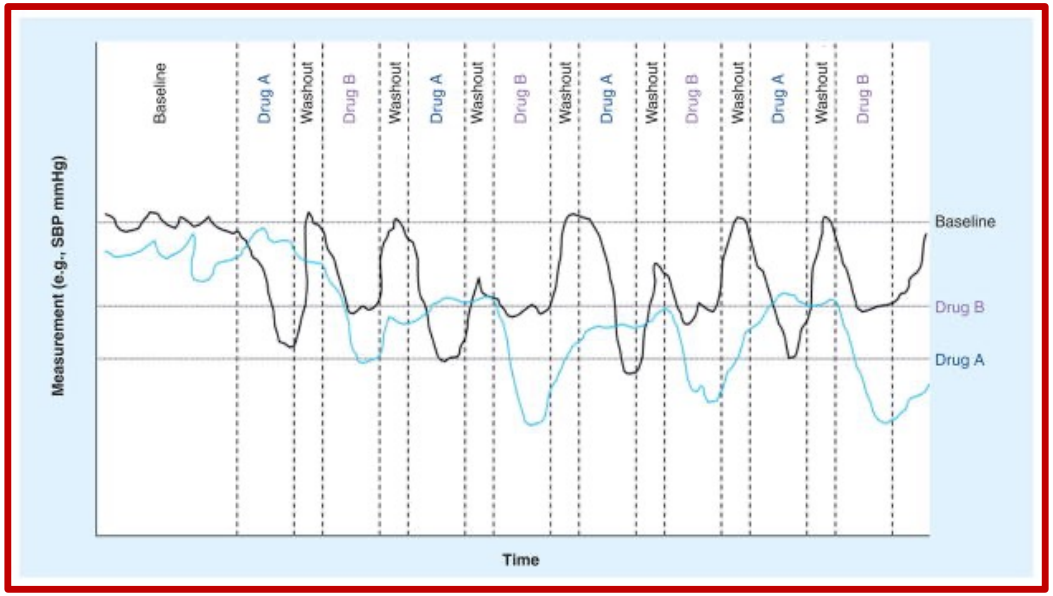


Reporting guidelines for main study types		
Randomised trials	CONSORT	Extensions
Observational studies	STROBE	Extensions
Systematic reviews	PRISMA	Extensions
Study protocols	SPIRIT	PRISMA-P
Diagnostic/prognostic studies	STARD	TRIPOD
Case reports	CARE	Extensions
Clinical practice guidelines	AGREE	RIGHT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

CONSORT extensions: Cutting-edge and relevant!

Extensions dedicated to TM:

- Acupuncture (STRICTA),
- Herbal interventions
- Chinese Herbal Medicine Formulas
- **Cupping (STRICTOC),**
- **Tuina/Massage (STRICTOTM)**
- **N-of-1 and N-of-1 TCM** (单个患者多重交叉设计)
  (Single patient, multiple cross-over design)

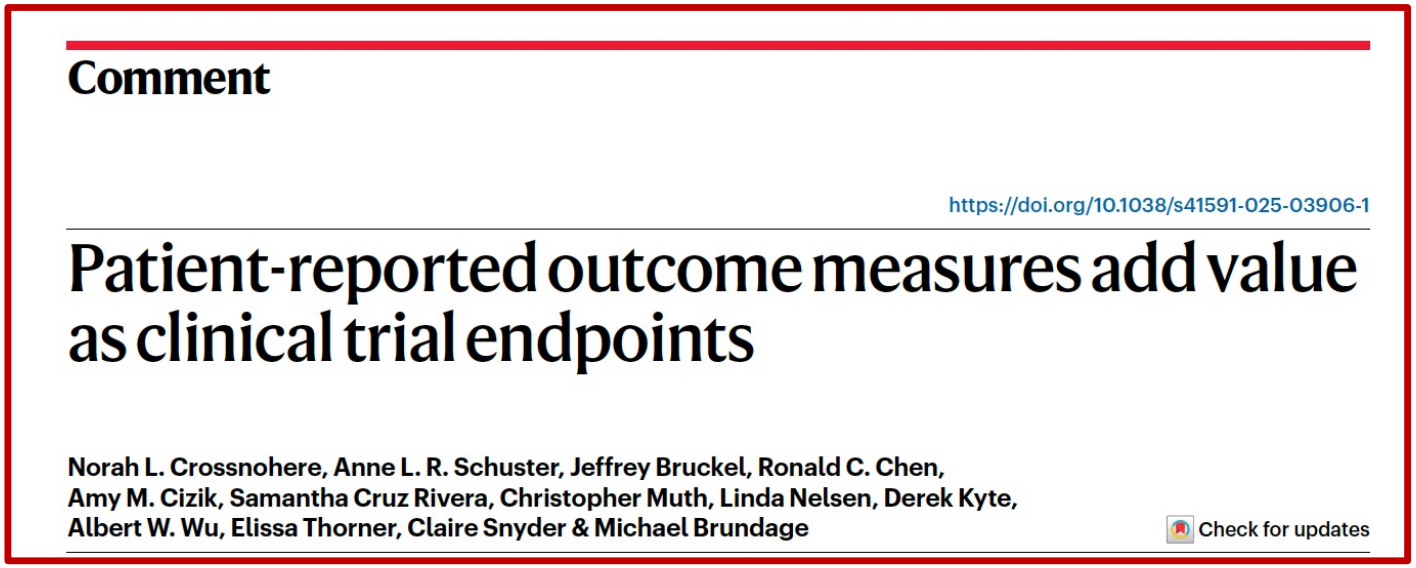


https://www.equator-network.org (accessed 02/12/2025)

equator network

The CONSORT- PRO extension

(Reporting patient-reported outcomes)



Comment

https://doi.org/10.1038/s41591-025-03906-1

Patient-reported outcome measures add value as clinical trial endpoints

Norah L. Crossnohere, Anne L. R. Schuster, Jeffrey Bruckel, Ronald C. Chen, Amy M. Cizik, Samantha Cruz Rivera, Christopher Muth, Linda Nelsen, Derek Kyte, Albert W. Wu, Elissa Thorner, Claire Snyder & Michael Brundage

Check for updates

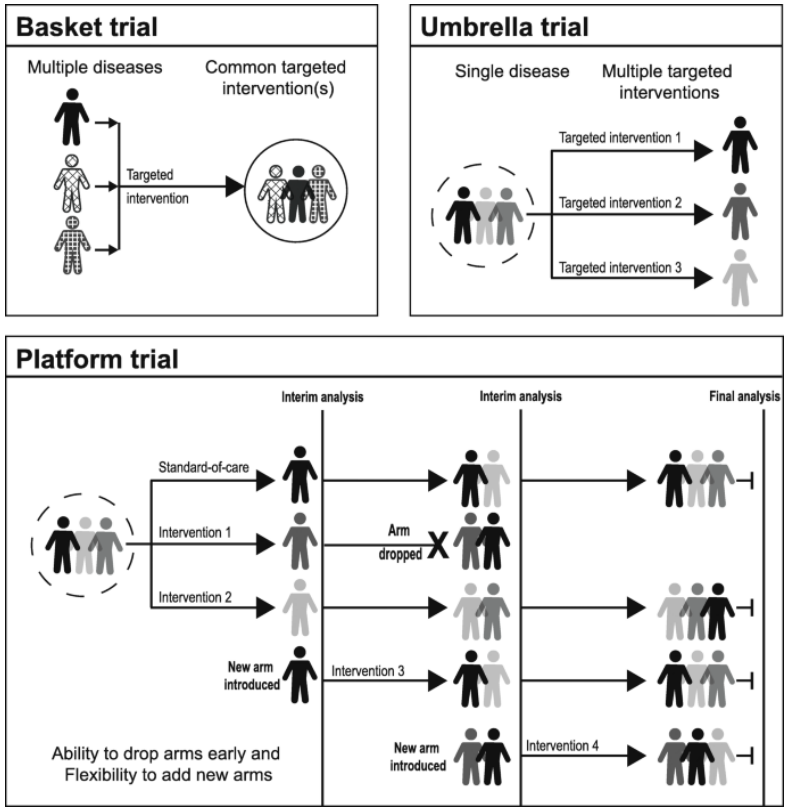
https://www.equator-network.org
(accessed 02/12/2025)

Patient-reported outcome measures add value as clinical trial endpoints.
Crossnohere NL, et al. Nat Med. 2025 Nov;31(11):3601-3604.

Innovative RCTs: basket（篮子）, umbrella（雨伞）, Platform（平台） trials

篮子：异病同治

Basket: One drug for 2 or more disorders



雨伞

平台

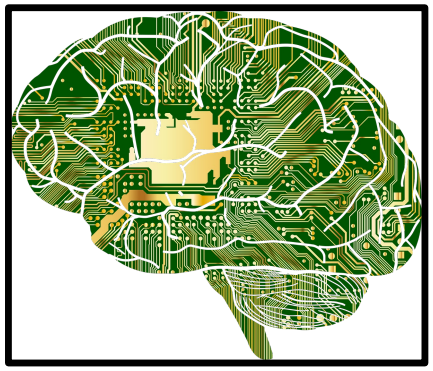
同病异治

Umbrella & Platform: 2 or more drugs for the same disorder

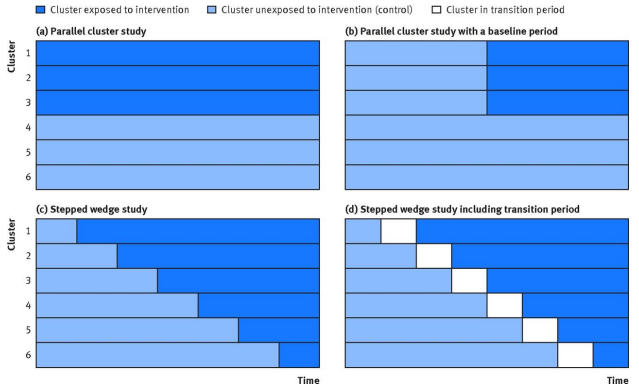
https://www.equator-network.org (accessed 02/12/2025)

Extensions on more “real-world like” RCTs:

- Artificial intelligence (人工智能)
- De-centralized trials（去中心化临床研究）
- Adaptive designs（适应性设计）
- Pragmatic trials（实效性临床研究）
- Cluster & stepped wedge cluster（集簇设计、阶梯集簇设计）





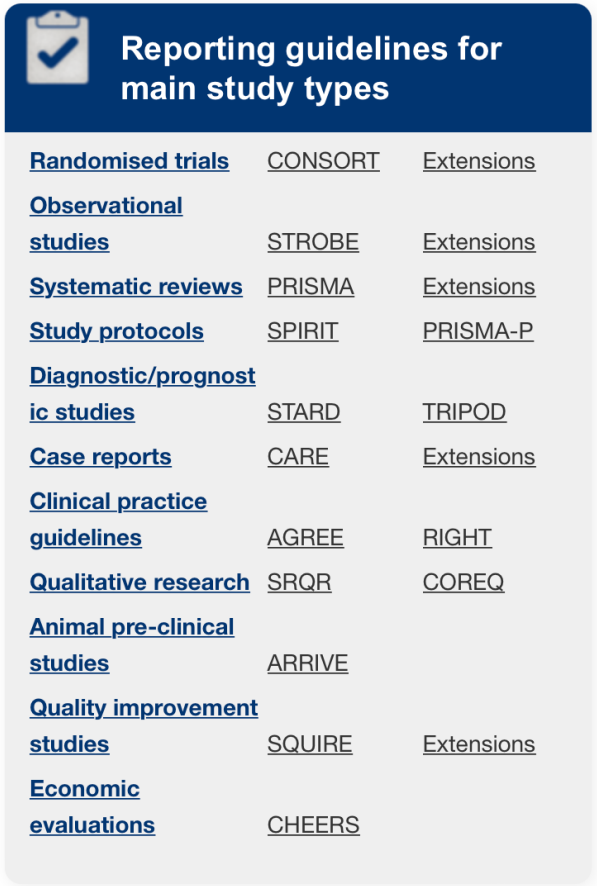


https://www.equator-network.org (accessed 02/12/2025)

equator network

A cross-sectional study of the endorsement proportion of reporting guidelines in 1039 Chinese medical journals. Duan Y, et al. *BMC Med Res Methodol.* 2023;23:20.

- By 2022, 24.1% endorsed CONSORT; 0.8% endorsed CONSORT extensions.
- 14.8-17.2% endorsed STROBE, PRISMA, STARD, CARE:
- <0.7% endorsed SPIRIT, TRIPOD, AGREE and RIGHT



https://www.equator-network.org (accessed 02/12/2025)

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Guideline implementation is far from satisfactory

草药质控的指南落实情况令人担忧

Shepherd A, Brunckhorst O, Ahmed K, Xu Q.
Botanicals in health and disease of the testis and male fertility: A scoping review.
Phytomedicine. 2022;106:154398.

- Only 9%-23% provided information on voucher samples, botanical authentication, extraction methods and chemical profiling!

Poor guideline implementation in RCTs

- Only 38% RCTs registered RCT protocols;
- Only 38% RCTs reported concealment of allocation and blinding of personnel involved in the trial.
- Only 43% RCTs reported ADR satisfactorily.
- Only 72% RCTs reported randomization methods.
- Only 78% RCTs reported ethical approval, but this was only 40% in those published in Chinese.
- Most RCTs reported written consent, but just a few published in Chinese.

Shepherd A, et al. *Phytomedicine*. 2022;106:154398.

The King's Centre for Integrative Chinese Medicine

Integrating Wisdom | Catalysing Innovation

https://www.kingscicm.org/

King's CICM is dedicated to disseminating TCIM-related guidelines & standards.
Please visit the "Sharing" & "Publications" columns of our website.



"We are what we share."

Professor Ian Sutherland, Brunel University London, Former UK Regional Coordinator, the Consortium for Globalization of Chinese Medicine

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CONCLUSIONS

- >1,600 IS/IGPG relevant to TCIM are published; more is coming.
- They are essential instruments to facilitate quality research and to advance integrative medicine.
- Let's build the future of ICM using these invaluable tools.

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