Synergies between Chinese and Western Medicine in Hong Kong and Beyond
Historical and Contemporary Perspectives

Third Bernard H. K. Luke Memorial Lecture in Hong Kong Studies:

Integrative Medicine from China to the World – 2
Good Practice, Regulations & Scientific Innovation

Prof Vivian Taam Wong JP
School of Chinese Medicine, LKS Faculty of Medicine, HKU
26 April 2019

Good Practice, Regulations & Scientific Innovation

1. Good Practice in Traditional Chinese Medicine (GPTCM)
2. Pharmacological Regulations and Vigilance
3. Disease - ‘Zheng’ and Network Pharmacology
4. Old Formulae for Major Disease Burden

How do we assess health safety and legality?

OPEN ACCESS Freely available online

PLoS GENETICS

Deep Sequencing of Plant and Animal DNA Contained within Traditional Chinese Medicines Reveals Legality Issues and Health Safety Concerns 2012

Megan L. Coghlan[1], James Haile[1], Jayne Houston[1], Dáithí C. Murray[1], Nicole E. White[1], Paula Moolhuijzen[2], Matthew I. Bellgard[2], Michael Bunce[1]*

1 Australian Wildlife Forensic Services and Ancient DNA Laboratory, School of Biological Sciences and Biotechnology, Murdoch University, Murdoch, Australia, **2** Centre for Comparative Genomics, Murdoch University, Murdoch, Australia

- High throughput sequencing (HTS) of DNA used to genetically audit, using plant reference databases.
- 15 'TCM' (powders, tablets capsules, bile flakes, tea) revealed 68 plant families including genera such as Ephedra & Ascarum that are potentially toxic.
- Animal genera identified as vulnerable to critically endangered, contravening Convention on International Trade in Endangered Species (CITES): Asiatic black bear & Saiga antelope; Bovidae, Cervidae, Bofonidae.

Good Practice in Traditional Chinese Medicine (GPTCM)

Opinion leader on state of the art and good practice

The GP-TCM *JEP* Special Issue 2012

20 papers on state of art & GxPs,
40 citations each in average

Xu Q & Bauer R, eds. J Ethnopharmacol 2012;140(3):1-642

WP10 (Manangement team)
No.1 – Good Practices: The basis for evidence-based medicines
No. 2 – Good practice and grand issues in TCM research
No. 3 – Good practice in reviewing and publishing TCM literature

WP1/WP2
(Quality control, extraction and chemical analysis of Chinese herbal medicine (CHM)
No. 4 – *"Daodi"* Chinese material medica (CMM)
No. 5 – Extraction and chemical analysis of CHM/complex herbal products (CHP)

WP3 (Toxicology of CHM)
No. 6 – Toxicological methods and toxicology of selected CHM
No. 7 – Pharmacovigilance in China
No. 8 – Pharmacovigilance in the West

WP4/WP5 (*In-vitro* and *in-vivo* studies of CHM)
No. 9 – *In-silico* studies of CHM
No. 10 – Omics in *in-vitro* and *in-vivo* CHM studies
No.11 – CHM studies using animal models

WP6 (Clinical studies of CHM)
No. 12 – Guidelines for randomised controlled trials
No. 13 – Comparison between TCM decoctions and granules

WP7 (R&D and regulation of CHM)
No. 14 – Regulation of CHP worldwide
No. 15 – Omics in regulatory science and Implications to CHP

WP8 (acupuncture)
No. 16 – Omics and acupuncture
No. 17 – A survey on traditional acupuncture practice

Independent reviews
No. 18 – PHY906 in the US, complementary to WPs 1-7
No. 19 – Value formation of herbal products, complementary to WPs 1-7
No. 20 – TCM syndrome differentiation, complementary to all WPs 1-8

Good Practice in Traditional Chinese Medicine (GPTCM)

Good practice in reviewing and publishing studies on herbal medicine, with special emphasis on traditional Chinese medicine and Chinese materia medica
中药研究专业用词的规范

Kelvin Chan, Debbie Shaw, Monique S.J. Simmonds, Christine J. Leon, Qihe Xu, Aiping Lu, Ian Sutherland, Svetlana Ignatova, You-Ping Zhu, Rob Verpoorte, Elizabeth M. Williamson, Pierre Duez.

J Ethnopharmacol 2012;140:469–75 **92 citations**

Good Practice in Traditional Chinese Medicine (GPTCM)

The formation of *daodi* medicinal materials

道地草药的丰富内涵和深远意义

Zhongzhen Zhao, Ping Guo, Eric Brand

J Ethnopharmacol 2012;140:476–481

40 citations

Good Practice in Traditional Chinese Medicine (GPTCM)

Royal Botanic Gardens Kew

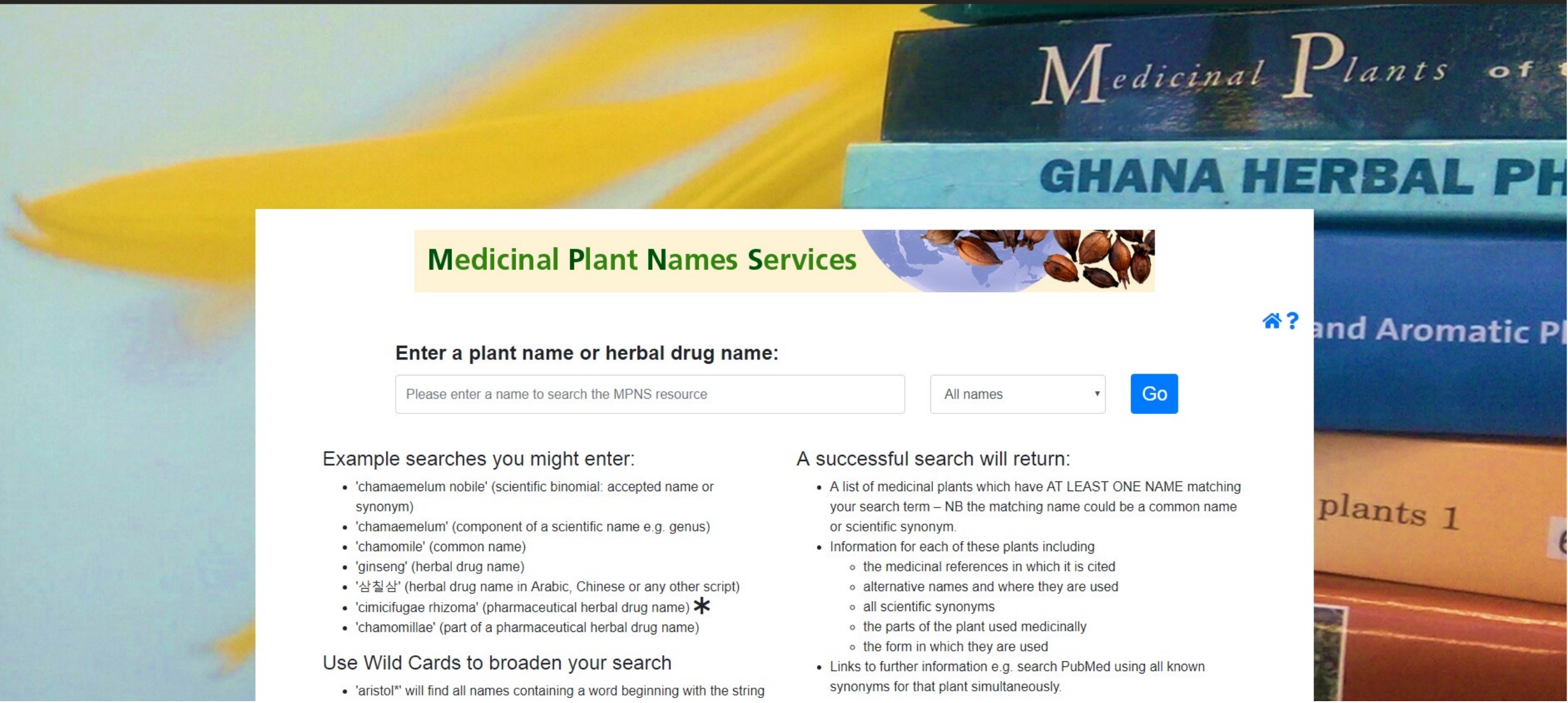
KEW GARDENS | WAKEHURST | KEW SCIENCE | READ & WATCH | LEARNING | JOIN & SUPPORT | SHOP

Home > Kew Science > Our science > Science services > **Medicinal Plant Names Services**

Medicinal Plant Names Services

A global nomenclatural indexing and reference service for medicinal plants aimed at those involved in global health, regulation and research.

Our Medicinal Plant Names Services (MPNS) provides a global nomenclatural indexing and reference resource enabling health professionals and researchers to access information about plants and plant products relevant to pharmacological research, health regulation, traditional medicine and functional foods. The MPNS



Medicinal Plant Names Services

Enter a plant name or herbal drug name:

Please enter a name to search the MPNS resource

All names

Go

Example searches you might enter:

- 'chamaemelum nobile' (scientific binomial: accepted name or synonym)
- 'chamaemelum' (component of a scientific name e.g. genus)
- 'chamomile' (common name)
- 'ginseng' (herbal drug name)
- '삼칠삼' (herbal drug name in Arabic, Chinese or any other script)
- 'cimicifugae rhizoma' (pharmaceutical herbal drug name) *
- 'chamomillae' (part of a pharmaceutical herbal drug name)

Use Wild Cards to broaden your search

- 'aristol*' will find all names containing a word beginning with the string

A successful search will return:

- A list of medicinal plants which have AT LEAST ONE NAME matching your search term – NB the matching name could be a common name or scientific synonym.
- Information for each of these plants including
  - the medicinal references in which it is cited
  - alternative names and where they are used
  - all scientific synonyms
  - the parts of the plant used medicinally
  - the form in which they are used
- Links to further information e.g. search PubMed using all known synonyms for that plant simultaneously.

Global Medicinal Plants

~**60,000 species** used globally medicinally

~**28,000** have well-documented use

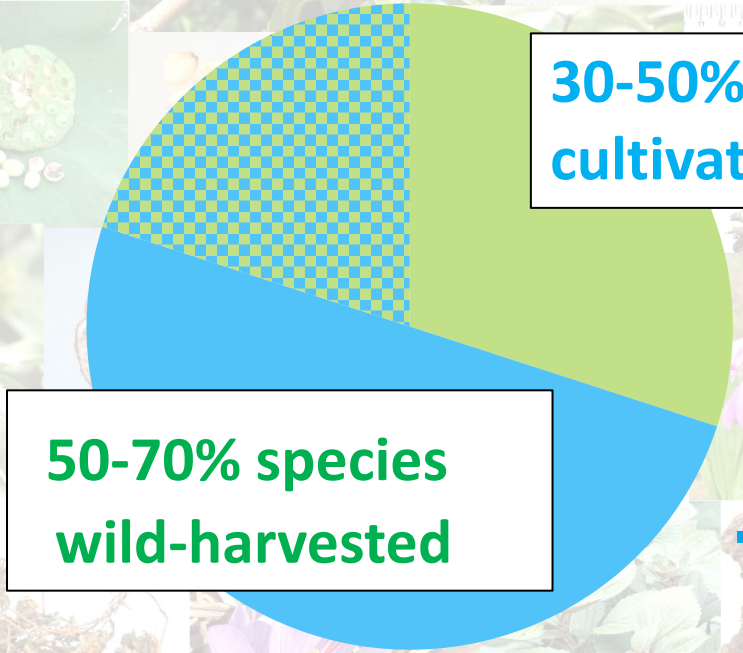
~**3,000 spp** traded internationally

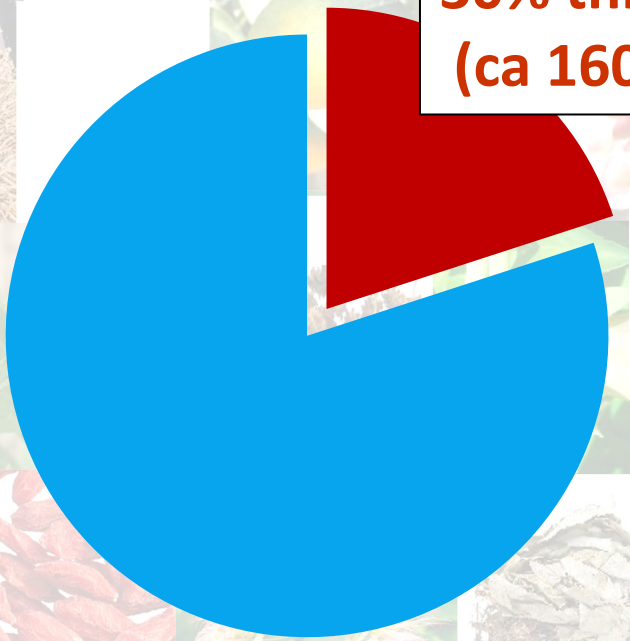
~**1/3** is commercially **cultivated**

State of the World's Plants Report 2017
Royal Botanic Gardens Kew

Chinese Pharmacopea Materia Medica 2015

614 plant species (CP 2015)



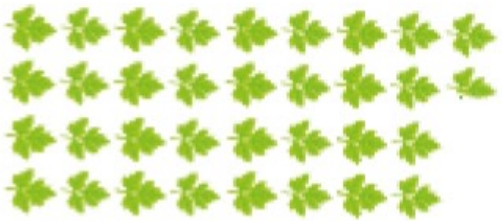


- over-harvesting
- habitat loss
- ?climate change

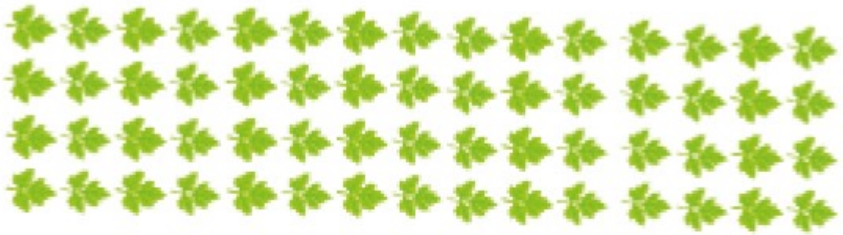
IUCN Red List 2018; Qin *et al*. 2017 *Biodiversity Science* 25(7); Leon & Lin 2017

Increasing global medicinal plants trade

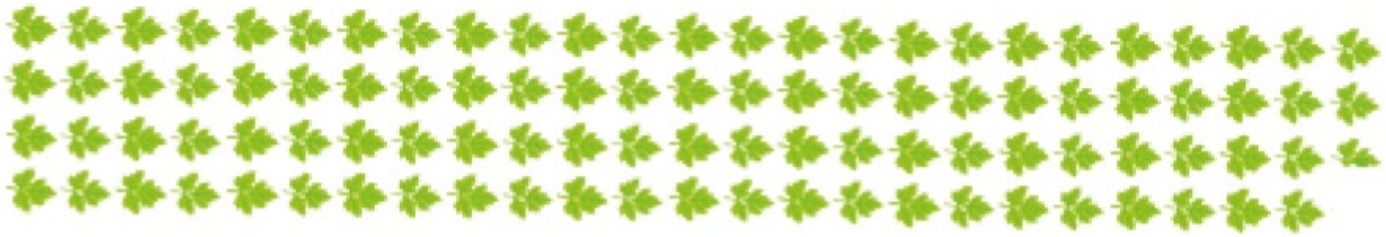
US$ 1.1billion
1999



US$ 1.8billion
2009



US$ 3billion
2015



TOP IMPORTERS

Hong Kong SAR
USA
Germany
Japan
China

TOP EXPORTERS

China
India
Canada
Germany
USA

UN Comtrade Data, 2018

1988 IUCN-WHO-WWF Guidelines on the Conservation of Medicinal Plants

1988

"... urgent need for international cooperation & coordination ... to develop programmes for their **conservation & sustainable use**."

.... includes many proposals for conservation (*in situ* and *ex situ*) but no detail whatsoever on how to achieve sustainable harvesting.

Agronomists:
Conservation Campaigners:
Ecologists:
Ethnobotanists:
Health Policy-makers:
Horticulturists:
Legal Experts:

Park Managers:
Park Planners:
Pharmacognosists:
Plant Breeders:
Plant Genetic Resource Specialists:
Plant Pathologists:

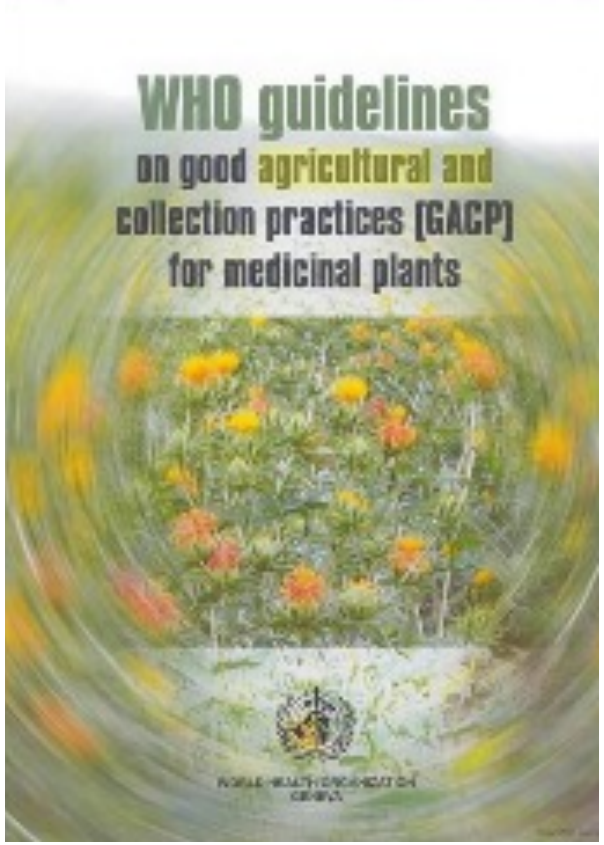
Religious Leaders:
Resource Economists:
Seed Biologists:

Taxonomists:
Traditional Health Practitioners:

20 disciplinary skills identified as essential

Can cultivated provenance be deduced from packaging?

Global 2003



collection of wild and semi-wild medicinal plants should conform to the practice of ***'MAXIMUM SUSTAINABLE YIELD'***

China 2002

Annex 1 China's
Good Agricultural Practice for Traditional Chinese Medicinal Materials - GAP State Drug Administration (SDA) 2002

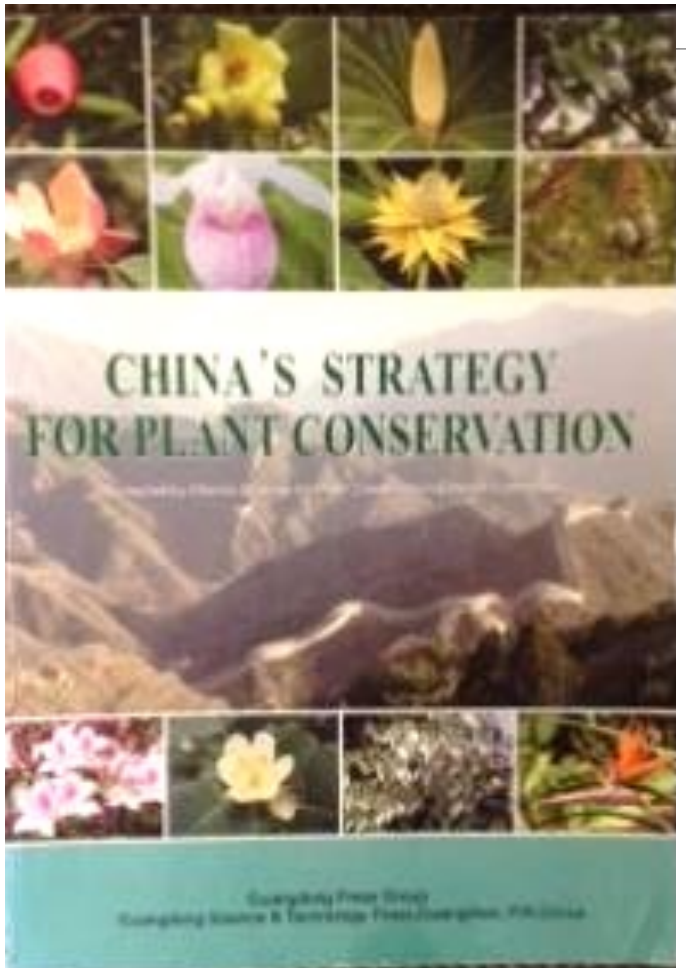
- One of first countries worldwide to establish GAP for medicinal herbs
- ~ 50 TCM species GA(C)P-certified
- Assurance of botanical identity, purity & cultivated provenance

BUT

- Japanese markets have monopoly on GAP TCM herbs
  (few GAP TCMs reach Europe)
- A further 150 TCM species cultivated WITHOUT GAP certification
- For these, 'cultivated provenance' is not required on labelling

Unless herbs are GAP-certified, responsible users (incl. researchers) cannot reliably discriminate cultivated from wild-sourced materials.

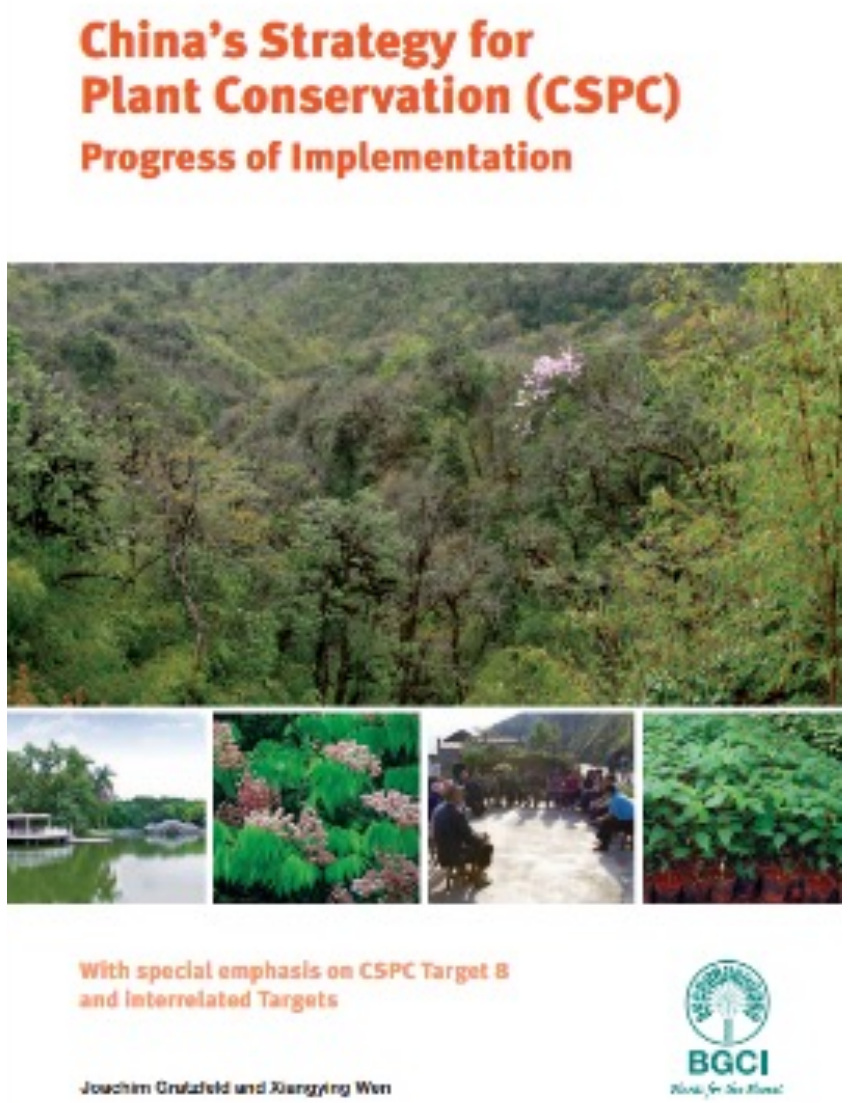
China's Strategy for Plant Conservation 2008 (SFA, CAS, SEPA)



2008

- National Medicinal Plant Germplasm Bank (Genetic Resource Base)
- No species of wild flora endangered by international trade
- designating Medicinal Plant Hotspots or strict protection
- 16 targets (in situ, ex situ incl. protected areas & safeguarding 5,000 threatened species
- Huge role of Botanic Gardens and IMPLAD network which: Rhizoma Gastrodiae (tian ma), Radix Panacis Quinquefolil (American ginseng), Rhizoma Coptidis (huang lian), and Fructus Amomi (sha ren)

China's Strategy for Plant Conservation (CSPC) 2012

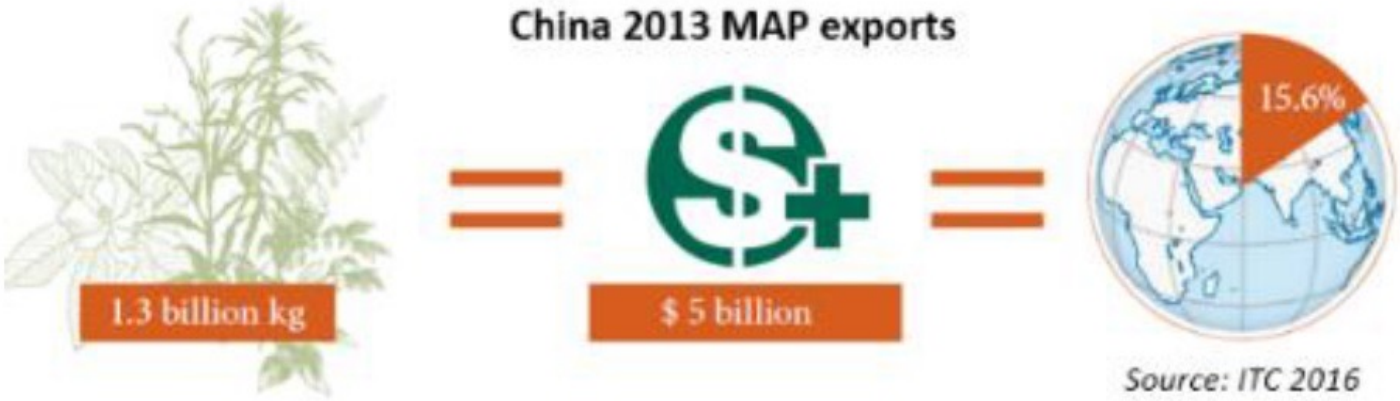


2012 review of progress
by international botanic garden community (BGCI)

Recommends 'strengthening intersectoral dialogue'
across all stakeholder groups
e.g. with China's medical agencies (CFDA, SATCM)

The importance of work on TCM sustainability

- China is the major importer and exporter of medicinal plants → global footprint
- Internal consumption and international trade;
- Importance and projected growth of TCM (including BRI)
- Best practices piloted → opportunity to deliver change
- Demand for FairWild certified products in EU and US, JP
- Interest of government and TCM industries to engage
- Potential for market access with high-quality, sustainable products



CSR TCM sector guidelines

- Cover sustainable supply chain management in TCM sector, developed through multiple stakeholder consultation, based on best practices

- Used to support TCM manufacturers (3) and traders (5) in the development of a long-term strategy and implementation roadmap for sustainable production and their commitment to the adoption of voluntary standards

http://www.traffic.org/egp-maps

Engaging China's Private Sector in Sustainable Management of Medicinal Plants

TRAFFIC
the wildlife trade monitoring network

TRAFFIC, the wildlife trade monitoring network, is the leading non-governmental organization working globally on trade in wild animals and plants in the context of both biodiversity conservation and sustainable development.

TRAFFIC is a strategic alliance between WWF and IUCN, leading the delivery of key components of their missions and programmes through a unique partnership that combines the considerable strengths of each of these two major global conservation organizations.

For more information visit www.traffic.org

EU – China (EGP)
Environmental Governance Program

The EU-China Environmental Governance Programme (EGP) is a €15 million EU-funded programme implemented with China's Ministry of Commerce and the Ministry of Environmental Protection. The programme is carried out by the Policy Research Centre for Environment and Economy (PRCEE) and runs from December 2010 until Dec 2015. The objective of the Programme is to enhance environmental governance in the People's Republic of China based upon the principles of the Aarhus Convention. It comprises four themes:

1. Public access to environmental information
2. Public participation in environmental planning and decision making
3. Access to justice in environmental matters
4. Corporate environmental responsibility

EU – China Environmental Governance Program (EGP)

The Local Component comprises 15 local partnership projects in which European entities work together with local governments in different parts of China. Each partnership project introduces a European approach to one of the fours themes indicated above in order to test and put into practice new ideas on environmental governance.

The National-level Component acts as an umbrella to the Local Component. It extracts and brings the result and policy implications of the partnership projects to a platform set by the Ministry of Environmental Protection. These are used for consideration in policy modification and for replication in other parts of China.

Further details of EGP activities and partnership projects can be found on the EGP website: www.ecegp.com

China's Traditional Chinese Medicine (TCM) & the Medicinal & Aromatic Plants (MAPS) Trade

MAPs (China Trade Data for 2013 exports)	kg	% of total volume	US($)	% of total value
Cultivated	1,086,138,364	80.9%	3,409,355,209	63.1%
Wild-collected and some cultivation	171,777,258	12.8%	1,453,192,877	26.9%
Cultivation and some wild-collected	54,299,824	4.0%	314,006,933	5.8%
Not known	21,805,367	1.6%	142,335,767	2.6%
Wild	8,435,445	0.6%	85,749,242	1.6%
Total:	**1,342,456,258**		**5,404,640,028**	

Wild and cultivated species of MAPs in China Trade Data for 2013 exports, Brinckmann 2015

China’s Traditional Chinese Medicine (TCM) & the Medicinal & Aromatic Plants (MAPS) Trade

Figure 2. Top 25 export destinations in medicinal plants (HS 1211) by volume from China in 2013, in kg (based on UN Comtrade data 2015)

What are the markets for sustainably sourced MAPs?

- Chinese MAPs may have the highest export market potential if they were commercially available with dual certification (organic + fair)
- A link to the market for **genuine origin or geographical indication products** promoted with a specified authentic and **'wild' quality and support claims about quality, traceability and efficacy of TCM ingredients**
- There may be a current market for anywhere from 5% to 15% of China's total MAP exports (about 65.1 million kg to 195.4 million kg) with organic certification of which about 5% to 10% (**3.3 million kg to 19.5 million kg) may have additional market opportunities if certified FairWild**

Ongoing work in Guangxi, Jilin, and Sichuan

- Pilot of the FairWild certification in China
  - *Gynostemma pentaphyllum*
  - *Dendranthema indicum*
  - *Schisandra* spp
- Development of resource inventories, species and area management plans and training materials
- Capacity-building for the sustainable wild harvesting and trade practices
- TCM industry engagement and trainings

A project supported by the Critical Ecosystem Partnership Fund (CEPF)

Enabling the use of the FairWild certification scheme in China

- Formal registration of the FairWild Standard with the government agency Certification and Accreditation Administration of the People's Republic of China (CNCA)
- China Standard Conformity Assessment Co., Ltd (CSCA) accredited as the exclusive certifier for FairWild in the People's Republic of China from 10/2017

Good Practice, Regulations & Scientific Innovation

1. Good Practice in Traditional Chinese Medicine (GPTCM)
2. Pharmacological Regulations and Vigilance
3. Disease - ‘Zheng’ and Network Pharmacology
4. Old Formulae for Major Disease Burden

Future development of global regulations of Chinese herbal products

草药制品政府监管的全球比较

Tai-Ping Fan, Greer Deal, Hoi-Lun Koo, Daryl Rees, He Sun, Shaw Chen, Jin-Hui Dou, Valery G. Makarov, Olga N. Pozharitskaya, Alexander N. Shikov, Yeong Shik Kim, Yi-Tsau Huang, Yuan Shiun Chang, William Jia, Alberto Dias, Vivian Chi-woon Wong, Kelvin Chan.

GP-TCM

WP7 Review on
Future development of global
regulation of Chinese herbal products

J Ethnopharmacol 2012;140:568–586

60 citations

Involvement of Pharmaceutical Companies in R&D in Medicinal Plants

Suspended

Abbott 雅培
Astellas 安斯泰來
Bayer 拜耳
Boehringer-Ingelheim 勃林格殷格翰
Bristol-Myers Squibb 百時美施貴寶
Lilly 禮來
GlaxoSmithKline 葛蘭素史克
Johnson & Johnson 強生
Merck Sharp & Dohme 默克
Novo Nordisk 諾和諾德
Pfizer 輝瑞
Roche 羅氏
Samkyo 三共株式會社
Sanofi-Aventis 賽諾菲安萬特

History:
60,000 medicinal plants screened → 135 candidates

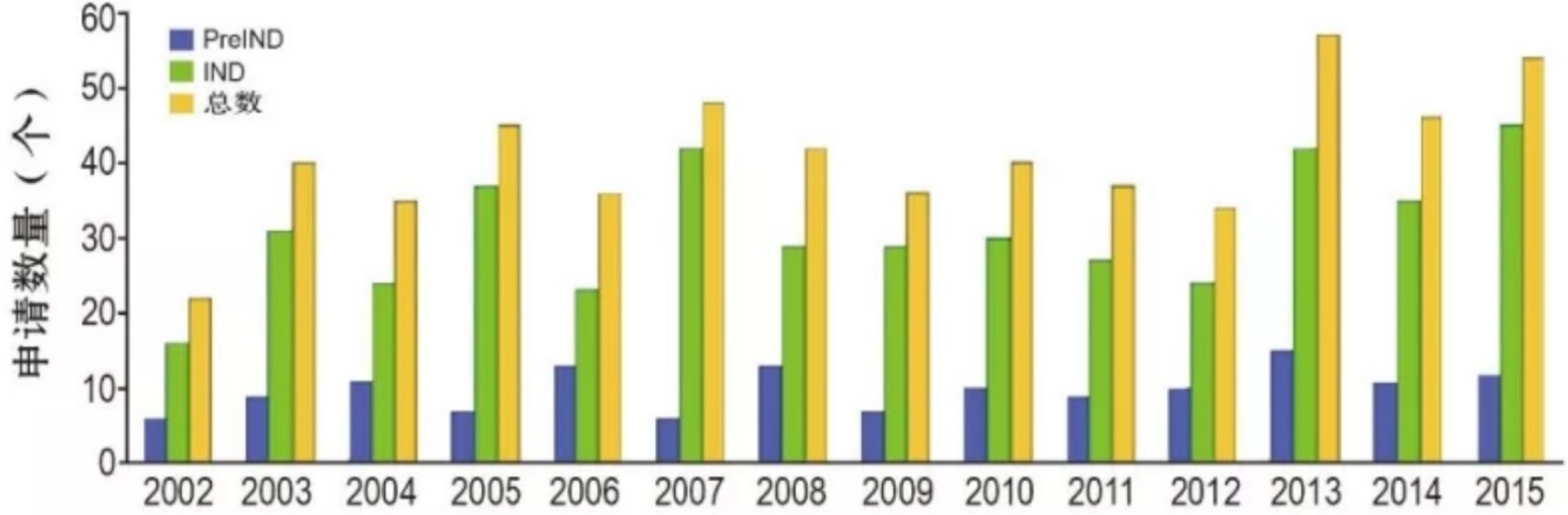
Global Reserve:
240,000 – 290,000 plants → 540 – 653 potential candidates

Continued

Dabur 達布爾製藥
Eisai 衛材製藥
Novartis 諾華
Otsuka 大塚製藥
Pierre Fabre 皮埃爾法布爾製藥
Piramal Pharma 匹拉摩製藥

Pharmacological Regulations and Vigilance

2002-2015 FDA Pre-IND, IND for Medicinal Plants



Cancer 34%
Metabolic 7%
Antiviral 4%
Anti-infection 3%

Skin & Dental 10%
Gastrointestinal 7%
Urological 4%
Neurological 3%

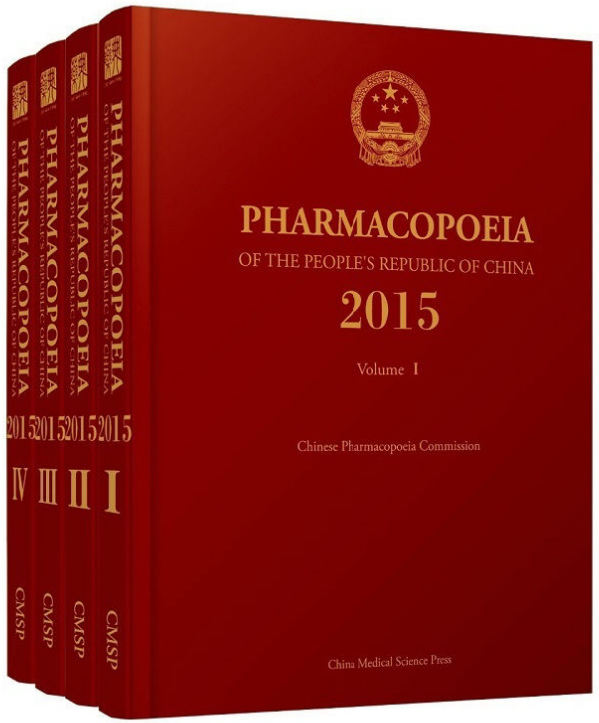
Pain & Anesthesia 10%
Respiratory 7%
Cardiovascular 4%
Others 7%

Pharmacological Regulations and Vigilance

TCM products under evaluation by US FDA, Sweden and licenses granted by Netherlands and Canada

Product	Company	Status
複方丹參滴丸 (Dantonic) (丹通尼克膠囊)	天士力製藥廠 Tasly Pharma.	FDA IND Phase III (Claimed Complete)
血脂康膠囊 (XueZhiKang)	北京北大維信生物科技有限公司	FDA IND Phase III
扶正化瘀片(Fuzheng Huayu)	上海中醫藥大學 TCM U of Shanghai	FDA IND Phase II
桂枝茯苓膠囊 (KYG0395)	江蘇康緣藥廠 Jiangsu Kanion	FDA IND Phase IIb
杏靈顆粒 (Xingling Keli)	上海杏靈科技藥業 Shanghai Xingling	FDA IND Phase II
威麥靈膠囊 (Weimaining Capsult)	華頤藥業有限公司 HuaYi Pharma.	FDA IND Phase II
康萊特注射液 (Kanion)	浙江康萊特藥業 Kanglaite Pharma.	FDA IND Phase II
康萊特注注射液/膠囊(Kanion)	美國康萊特藥業 Kanglaite Pharma.	FDA IND Phase II
HMPL-004	Nutrition Science Partners	FDA IND Phase III
PHY906	Phytoceutica Inc.	FDA IND Phase II
濃縮當歸丸 (Nongsuo DangguiWan)	佛慈製藥 Foci Pharmaceuticals	Sweden Applied
心血康膠囊 Xin Xue Kang (2012)	**成都地奧製藥 Diao Pharmaceuticals**	**Dutch License**
樂脈顆粒 Lemai Keli (2012)	**華西藥業 West China Pharmaceuticals**	**Canadian License**
膽寧片 (2016)	**上海和黃藥業 Shanghai Hutchinson**	**Canadian License**

Pharmacological Regulations and Vigilance



Pharmacological Regulations and Vigilance

European Directorate for the Quality of Medicines and Healthcare (EDQM) signed a 4-year MOU with Chinese Pharmacopeia to set up joint executive committee and working groups to collaborate in ensuring the quality of medicine through:

- Exchanging scientific information and expertise
- Developing quality standards
- Training initiatives
- Exchange programs

COUNCIL OF EUROPE

COUNCIL OF EUROPE

edqm
European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

Home | About us | European Pharmacopoeia | Reference Standards | Certification of Suitability | OMCL Network | Transfusion & Transplantation | Patient & Consumer Health Protection

Home > About us > Newsroom > Chinese and European Pharmacopoeias set up Joint Executive Committee to collaborate on standards

Back

Chinese and European Pharmacopoeias set up Joint Executive Committee to collaborate on standards

EUROPEAN PHARMACOPOEIA PHARMACOPOEIAL HARMONISATION | NEWS | 04 SEPTEMBER 2017 | STRASBOURG, FRANCE

The European Directorate for the Quality of Medicines and HealthCare (EDQM) and the Chinese Pharmacopoeia Commission (ChP) today announced the signing of a new Memorandum of Understanding (MOU) for the next four years. This new agreement is aimed at promoting co-operation on the safety and quality of medicines in China and Europe. In particular, the agreement entails the setting up of a Joint Executive Committee, which will be composed of experts from both parties and will establish working groups as well as explore ways to collaborate on topics of common interest.

Under the MOU, the Pharmacopoeias will promote co-operation and coordinate activities related to their common objective of ensuring the quality of medicines. They will also consider exchanging scientific information and expertise on developing quality standards, strengthening already well established working relationships as well as contributing to the common development of EDQM and ChP through training initiatives and exchange programmes.

Susanne Keitel, Director of the EDQM, expressed satisfaction with the agreement and added that: "In an ever more globalised pharmaceutical sector, co-operation among international pharmacopoeias on quality standards is essential to ensure that the protection of public health is based on the best scientific expertise available worldwide."

The EDQM is the Directorate of the Council of Europe that ensures the basic human right of access to good quality medicines and healthcare in Europe. Its European Pharmacopoeia defines mandatory standards for the quality control of medicines and their components; it is legally binding in 38 European Member States (including the European Union).

Founded in 1950, the Pharmacopoeia Commission of China (ChPC) is tasked with drafting and revising the Chinese Pharmacopoeia. Its members are medical and pharmaceutical experts who remain in charge for a period of 5 years. This Chinese Pharmacopoeia provides the statutory requirements for pharmaceutical companies producing medicines for the Chinese market. Its latest edition came into effect on 1st December 2015.

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AGENDA

18 JUNE 2019 TO 20 JUNE 2019
SHANGHAI, CHINA
CPhI China & CEP One-to-One Sessions

19 JUNE 2019 TO 20 JUNE 2019
STRASBOURG, FRANCE
International Conference on the 'EDQM & European Pharmaco...

22 JUNE 2019 TO 26 JUNE 2019

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Categories

- [x] Herbal
- [ ] Human (7456)
- [ ] Veterinary (1174)

Herbal substance (Latin name)

Herbal botanical name of plant

Herbal substance (English common name)

Herbal status

194 results

Sort by: Relevance (descending)

Remove all filters

CATEGORIES: Herbal

Herbal medicinal product: Malvae folium (updated)

Malva sylvestris L., Mallow leaf, F: Assessment finalised

Herbal medicinal product: Malvae sylvestris flos (updated)

Malva sylvestris L., Mallow flower, F: Assessment finalised

Herbal medicinal product: Cynarae folium (updated)

Cynara scolymus L., Artichoke Leaf, F: Assessment finalised

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Objectives

In order to address the aforementioned key trends and new issues the following objectives should be achieved.

Objective 1: To improve the output of the Committee on Herbal Medicinal Products, in particular by increasing the quality and number of Monographs and List entries

The following shall be addressed:

1. In collaboration with stakeholders, **adjust the priority list** of herbal substances, preparations and combinations thereof for assessment to the **needs of the market operators** and **allocate Member States resources accordingly.**

Action Plan for Herbal Medicines 2010-2011

Key trends and new issues

- The issues raised in the European Commission's Report on the experience acquired as a result of the application of the provisions of Chapter 2a of Directive 2001/83/EC (introduced by Directive 2004/24/EC) on specific provisions applicable to traditional herbal medicinal products need to be addressed. In particular, improvement concerning the genotoxicity data situation shall be sought.
- A possible extension of the scope of Directive 2004/24/EC has been proposed by the European Commission and is supported by the Herbal Medicinal Products Committee (HMPC), i.e. the simplified registration procedure could be opened to other traditional products of a long standing tradition in the EU, including certain products of animal origin.
- The Member States will face the end of the transition period by which they shall apply the provisions of Directive 2004/24/EC to traditional herbal medicinal products already on the market on 30 April 2004.
- Regular reports on the uptake of the traditional use registration scheme in the Member States shall be undertaken, in cooperation with the CMD-h.
- Any international request for collaboration in the field of herbal medicines and alternative treatments needs to be addressed, in close collaboration with the European Commission.

- Increase quality and number of monographs and list entries
- Assess the needs of the market operations
- Allocate member states resources

Pharmacological Regulations and Vigilance

一般社団法人 Kampo Medicine since 1950
日本東洋医学会

Japanese
FONT SIZE A A A

Home > Medical top > Related information > The Special Committee for EBM > Evidence Reports of Kampo Treatment 2013 > 1.Lists of structured abstracts

Evidence Reports of Kampo Treatment 2013 : 402 RCT (EKAT 2013)

- Notes on the current version
- History of version upgrades
- Excecutive summary
- **1. Lists of structured abstracts**
- 2. Background
- 3. Purpose
- 4. Steps for development of structured abstracts
- 5. Included and excluded references
- 6. Relation to other projects
- 7. Lists of excluded references
- 8. Conflict of interests
- 9. Organization
- 10. Acknowledgements
- 11. Contact point
- Full Text (PDF)

released 7 Sep 2017

1. Lists of structured abstracts

EKAT Appendix 2014
EKAT Appendix 2015

Structured astracts search
検索

Ⅰ. Structured Abstracts describing RCTs and the References Reporting Them

1. Infections (including Viral Hepatitis) (20 abstracts, 26 references)
2. Cancer (Condition after Cancer Surgery and Unspecified Adverse Drug Reactions of Anti-cancer Drugs) (31 abstracts, 37 references)
3. Blood Diseases including Anaemia (15 abstracts, 18references)
4. Metabolism and Endocrine Diseases (11 abstracts, 15 references)
5. Psychiatric/Behavioral Disorders (13 abstracts, 15 references)
6. Nervous System Diseases (including Alzheimer's Disease) (15 abstracts, 17 references)
7. Eye Diseases (4 abstracts, 5 references)
8. Ear Diseases (7 abstracts, 7 references)
9. Cardiovascular Diseases (15 abstracts, 18 references)
10. Respiratory Diseases (including Influenza and Rhinitis) (52 abstracts, 68 references)
11. Gastrointestinal, Hepato-Biliary-Pancreatic Diseases (70 abstracts, 92 references)
12. Skin Diseases (16 abstracts, 17 references)
13. Diseases of the musculoskeletal system and connective tissue (20 abstracts, 19 references)
14. Genitourinary Tract Disorders (including Climacteric Disorders) (37 abstracts, 43 references)
15. Ante/Post-partum Diseases (11 abstracts, 13 references)
18. Symptoms and Signs (27 abstracts, 38 references)
19. Injury, Poisoning, and Postoperative Pain (5 abstracts, 5 references)
21. Others (34 abstracts, 38 references)

Ⅱ. A Structured Abstract describing Meta-analysis and the Reference Reporting It

15. Ante/Post-partum Diseases (1 abstract, 1 reference)

Note: Original English titles assigned by authors were used in this list and the structured abstracts. When references had no English titles, the Task Force translated the original Japanese titles into English ones (*).

Abbreviations: C: The Cochrane Library (CENTRAL) J: *Igaku Chuo Zasshi / Japana Centra Revue*

Kampo Medicine since 1950 日本東洋醫學會 conducted 402 randomized controlled trials showing evidence reports of Kampo treatment in 2013 (updated in 2014, 2015).

Standards for manufacturing of Kampo for sale of common use

一般用漢方製剤製造販売承認基準

厚生労働省医薬・生活衛生局
平成 29 年 4 月 1 日

Pharmacovigilance practice and risk control of Traditional Chinese Medicine drugs in China: Current status and future perspective

草药安全监控现状和展望

Li Zhang, Jingbo Yan, Xinmin Liu, Zuguang Ye, Xiaohui Yang, Ronald Meyboom, Kelvin Chan, Debbie Shaw, Pierre Duez

J Ethnopharmacol 2012;140:519–25 **102 citations**

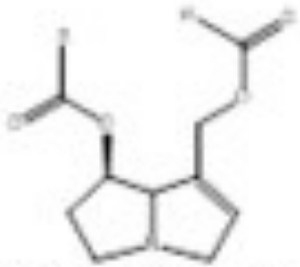
Review of current and “omics” methods for assessing the toxicity (genotoxicity, teratogenicity and nephrotoxicity) of herbal medicines and mushrooms

组学方法研究草药的毒性

Moustapha Ouedraogo, Thomas Baudoux, Caroline Stévigny, Joëlle Nortier, Jean-Marie Colet, Thomas Efferth, Fan Qu, Jue Zhou, Kelvin Chan, Debbie Shaw, Olavi Pelkonen, Pierre Duez

Conventional methods

Computer-assisted prediction

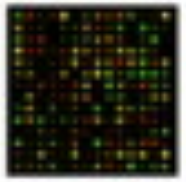


Structural alert for toxicity

In vitro methods

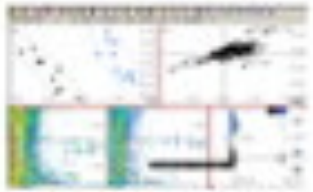
In vivo methods

“Omics” technologies



Transcriptomics

Proteomics



Metabonomics

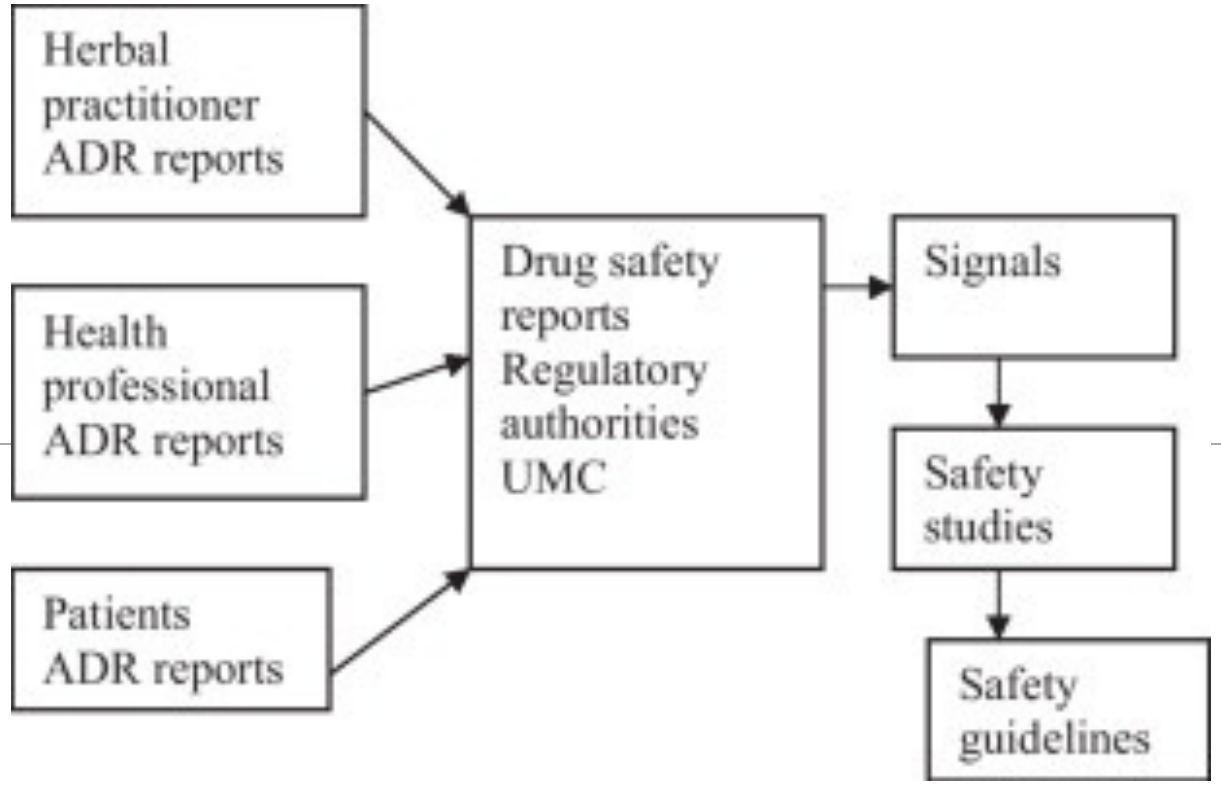
Methods for toxicity assessment of traditional herbal medicines

J Ethnopharmacol 2012;140:492–512 **Cited 90 times**

Pharmacovigilance of herbal medicine

中国以外地区草药安全的监控

Debbie Shaw, Ladds Graeme, Duez Pierre, Williamson Elizabeth, Chan Kelvin



J Ethnopharmacol 2012;140:513–18 **106 citations**

Pharmacological Regulations and Vigilance

CM quality Q marks: theory & strategy to enhance research standards 2019

- The concept, core theory & research methods of CM quality markers
- A smart near-infra-red spectroscopy evaluation system for quality management of CM materials based on quality markers
- Research strategy for quality-biomarkers of TCM, based on benchmarks of effects
- A hypothesis on the Q-marks based on characteristics of opposite effect of herbs: an example of Sanqi
- Discovery of quality markers of TCM compounds and visualization technology of content-effect color atlas

Review

Use of nano-carriers for synergistic effect of chemotherapeutic drugs & CM active compounds

Good Practice, Regulations & Scientific Innovation

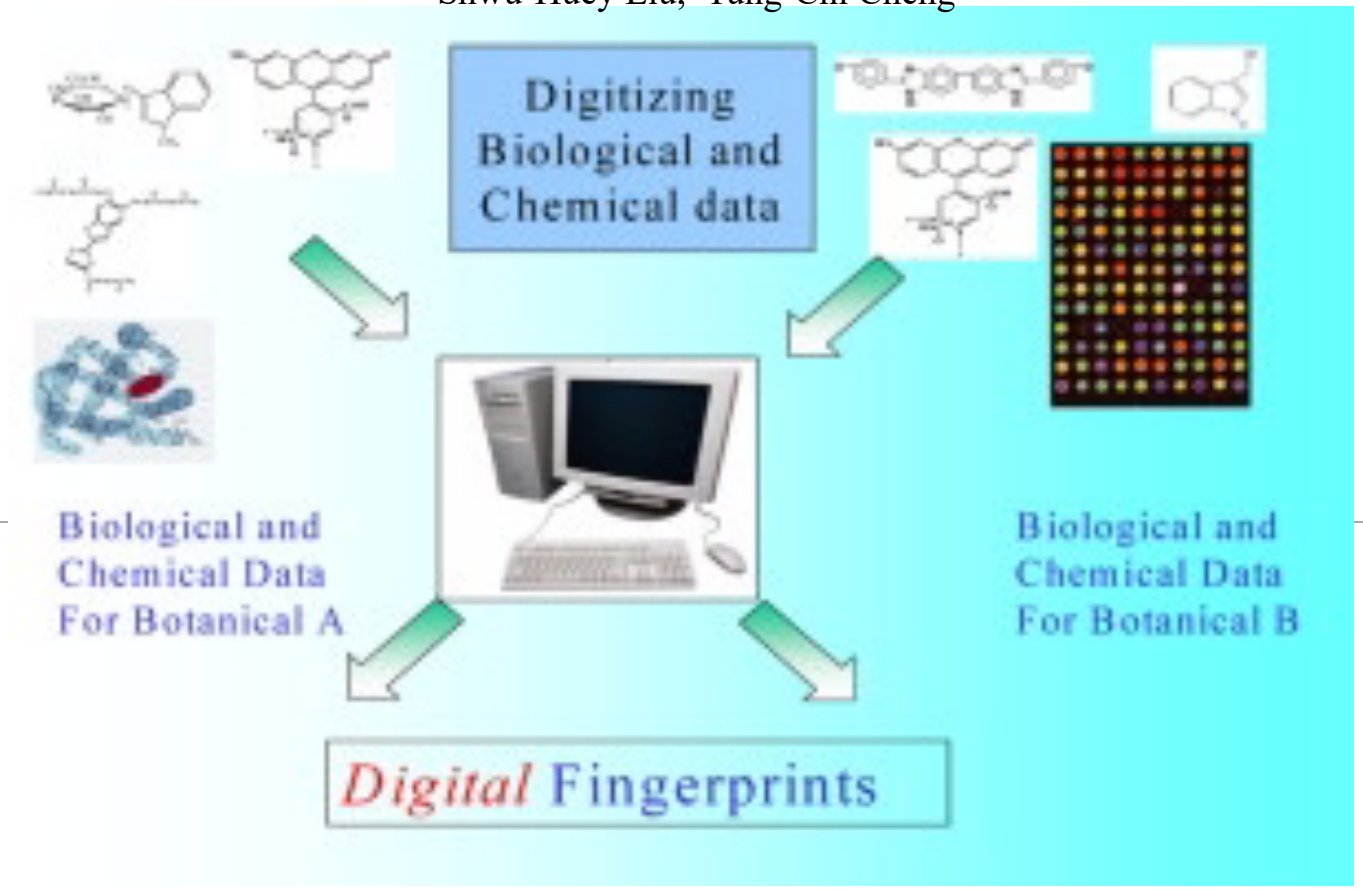
1. Good Practice in Traditional Chinese Medicine (GPTCM)
2. Pharmacological Regulations and Vigilance
3. Disease - ‘Zheng’ and Network Pharmacology
4. Old Formulae for Major Disease Burden

Disease - ‘Zheng’ and Network Pharmacology

Old formula, new Rx: The journey of PHY906 as cancer adjuvant therapy

草药现代化是可行的：黄芩汤为例

Shwu-Huey Liu, Yung-Chi Cheng

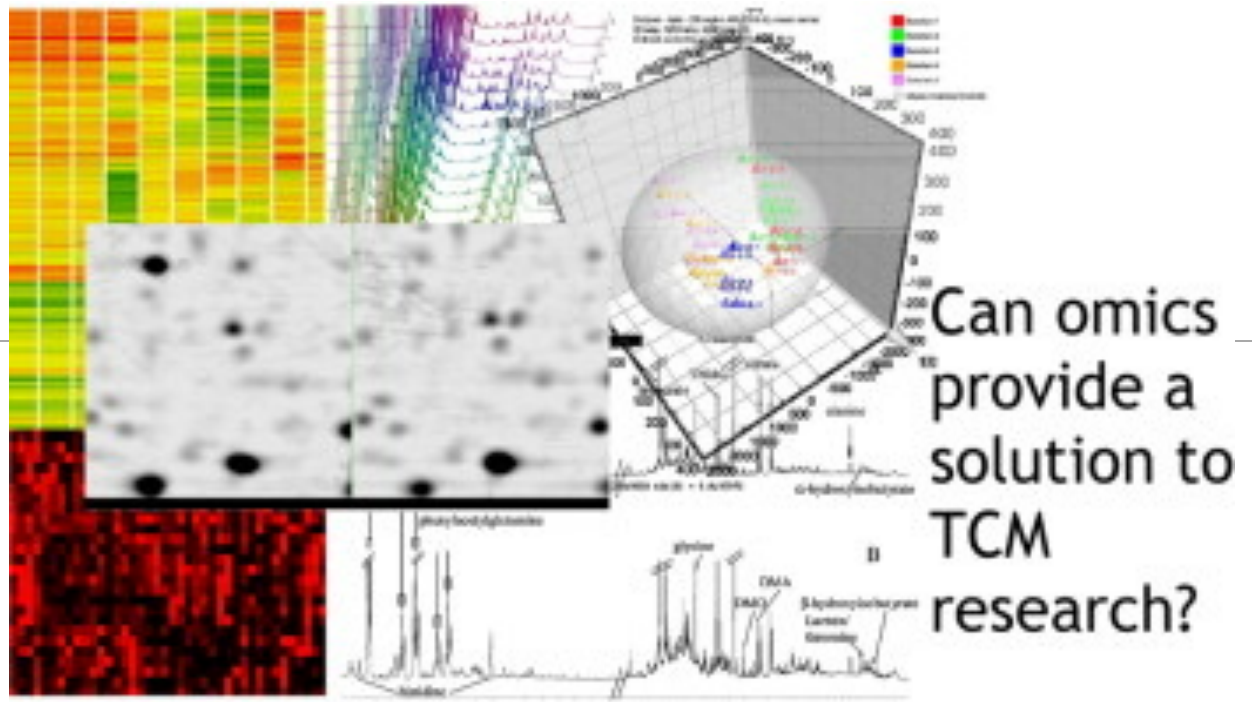


J Ethnopharmacol 2012;140:614–623 63 citations

Disease - ‘Zheng’ and Network Pharmacology

Omic techniques in systems biology approaches to traditional Chinese medicine research: Present and future
组学和系统生物学方法研究中药药理

Alessandro Buriani, Maria L. Garcia-Bermejo, Enrica Bosisio, Qihe Xu, Huige Li, Xuebin Dong, Monique S.J. Simmonds, Maria Carrara, Noelia Tejedor, Javier Lucio-Cazana, Peter J. Hylands



J Ethnopharmacol 2012;140:535–544 **Cited 106 times**

Disease - ‘Zheng’ and Network Pharmacology (World Journal of TCM)

A Visual Analysis of Network Pharmacology Research Trends

Shen Xiao[a], Fang-Qing Zhao[b], Qi-Ming Wang[b], Yun-Ru Dong[b], Shein-Chung Chow[c], Meng-Zhen Fan[b], Bo Xing[b], Fei Zhai[a], Rong-Wu Xiang[a]

[a]School of Medical Devices, Shenyang Pharmaceutical University, Shenyang, China, [b]School of Pharmacy, Shenyang Pharmaceutical University, Shenyang, China, [c]Department of Biostatistics and Bioinformatics, School of Medicine, Duke University, DUMC Box 2721, 2424 Erwin Road, Hock Suite 1102, Room 11068, Durham, NC 27710, USA

- Visual Analysis of external & internal characteristics of literature
- Using bibliometrics to build knowledge map of knowledge systems, research hotspots, dynamic frontiers, research status and trends.
- Now, at stage of formation & construction of basic theories, solution of disease problems & basic theoretical research.
- TCM is a new hotspot requiring connection & communication among knowledge groups for formation of a systematic knowledge system.

Disease - 'Zheng' and Network Pharmacology (World Journal of TCM)

Table 5: The information of emergent words in the past 5 years

Emergent words	Co-occurrence words	Emergence rate	Frequency	Year
Systems biology	Disease; Reconstruction	11.9475	28	2012
Organization	Saccharomyces cerevisiae; Biological Network; Metabolic Network; Functional module; Complex Network; Community Structure; Discovery; Modularity	11.5814	45	2012
Yeast	Algorithm; Complexe; Genome; Identification; Saccharomyces cerevisiae; PPI Network; Interaction Network; Bioinformatics, *et al*.	8.8882	89	2012
Metabolic Network	Complex Network; Organization; Identification	8.7317	83	2012
Carcinoma	Differentially Expressed Gene; Expression	7.9276	38	2015
Inflammation	Cell	7.7172	38	2015
Biology	Gene Ontology; Database	5.9173	37	2012
Community Structure	Biological Network; Complex Network; Organization	5.8968	45	2012
Complexes	PPI Network; Interaction Network; Algorithm; Yeast; Saccharomyces cerevisiae; Database	5.8813	40	2014
Saccharomyces cerevisiae	*Escherichia coli*; Yeast; Genome; Identification; Database; Discovery; Organization; Protein-protein Interaction; Mass Spectrometry; Complexe	5.0836	88	2012
Mechanism	Traditional Chinese Medicine; Apoptosis; Discovery	4.7501	57	2013
Traditional Chinese Medicine	Drug Discovery; Network Pharmacology; Cytoscape; Database; Mechanism; Signaling Pathway, *et al*.	2.6398	54	2013
Functional module	Organization; Identification; PPI Network; Algorithm; Interaction Network; Discovery; Biological Network; Database	2.496	56	2012
Algorithm	Discovery; Yeast; Prediction; Biological Network; Complexe; PPI Network; Gene Ontology, *et al*.	2.4669	100	2012

PPI: Protein-protein interaction

Disease - ‘Zheng’ and Network Pharmacology

Efficacy & Pharmacodynamics功效与药效: (complex & multiple)

TCM functional effects:
- the signs & symptoms,
- the Zheng
- the Disease

TCM physical effects:
- whole body,
- tissues & organs,
- cells,
- molecules

8 Mechanisms of pharmacological action:
- physico-chemical reaction,
- cellular metabolism,
- physiological substance transport,
- enzyme effect,
- ion channel on cell membrane,
- nucleic acid metabolism,
- immunological function
- non-specific.

Disease-Zheng Integrated Model for TCM Formulae複方病證結合: (methodology at multi-level)
- TCM clinical Zheng diagnostic standards
- therapeutic effectiveness evaluation methods
- integrate chemistry, bio-informatics & PK/PD techniques
- develop studies on mechanistic & material basis
- explain the pharmacological effects.

Disease - 'Zheng' and Network Pharmacology

Disease-Zheng integrated model for TCM formulae

12 animal models with 5 disease & 6 Zheng:
- Pig coronary artery disease Tan-Yu-Hu-Jie 痰瘀互结
- Rabbit arterial sclerosis/ stenosis Tan-Yu-Hu-Jie 痰瘀互结
- Rat cerebral thrombosis Luo-Mai-Yu-Zu 络脉瘀阻
- Rat Qi-Xu-Xue-Yu 氣虚血瘀
- Rat Qi-Zhi-Xue-Yu 氣滞血瘀

3 methods for evaluation of effectiveness
- Reflect the effect on the 4 diagnostic methods
- Measure the pathological or physiological parameters
- Use molecular marker groups for characterization

Benefits of the D-Z Integrated Model for Clinical Evaluation:
- Explains the functional & physical effects using biological basis
- Produces socio-economic benefits
- Advances the inheritance & innovation of TCM pharmacology

2 cellular models :
- Qi-Xu-Xue-Yu氣虚血瘀
- Qi-Zhi-Xue-Yu氣滞血瘀

Pharmacological evaluation system & platform with 83 models & 220 SOP, using 8 TCM Formulae

Treat 4 groups of diseases:
- cardio-cerebral artery,
- neuro-degenerative,
- diabetes & complications,
- cancer etc;

Address 4 Zheng:
- YI-Qi-Huo-Xue 益氣活血,
- Li-Qi-Huo-Xue 理氣活血,
- Qu-Yu-Hua-Tan 祛瘀化痰,
- Huo-Xue-Jie-Du 活血解毒

Disease - 'Zheng' and Network Pharmacology (World Journal of TCM)

Review Article

Network Pharmacology: An Approach to the Analysis of Complex Systems Underlying Traditional Chinese Medicine

- 1999 & 2002- association among TCM syndromes (ZHENG), herbal formulae & molecular networks
- 2007- ***Nature Biotechnology***, AL Hopkins: Network Pharmacology
- 2018 – ***WJTCM Special Issue*** on TCM & Network Pharmacology
- Approach to the analysis of complex systems underlying TCM: multiple components, targets, effects.
- The model visualizes and analyzes multi-layer interactions, including "component/compound/drug-target", "target-pathway" and "target-disease".
- For identification of the active ingredients, targets & underlying therapeutic mechanisms;
- And identification of new indications & innovative drugs.

Disease - ‘Zheng’ and Network Pharmacology (World Journal of TCM)

Review Article

Network Pharmacology: An Approach to the Analysis of Complex Systems Underlying Traditional Chinese Medicine

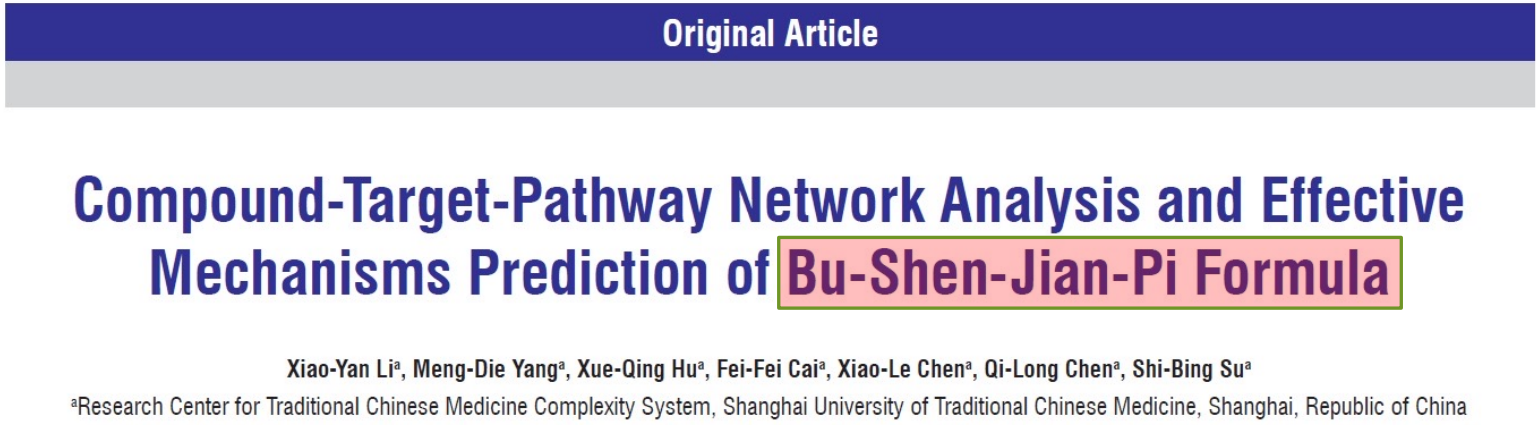
- Challenges: Repeatability Reliability Consistency,

to bridge the gap between traditional & modern medicine

1. Lack of sufficient reliable data on TCM compounds for construction of a sufficiently predictable network, despite databases produced by high throughput experimentation & computational modeling.

2. Scientific & robust validation based on chemical & biological experiments and predicted results of network analysis.

Disease - ‘Zheng’ and Network Pharmacology (World Journal of TCM)


Original Article

Compound-Target-Pathway Network Analysis and Effective Mechanisms Prediction of Bu-Shen-Jian-Pi Formula

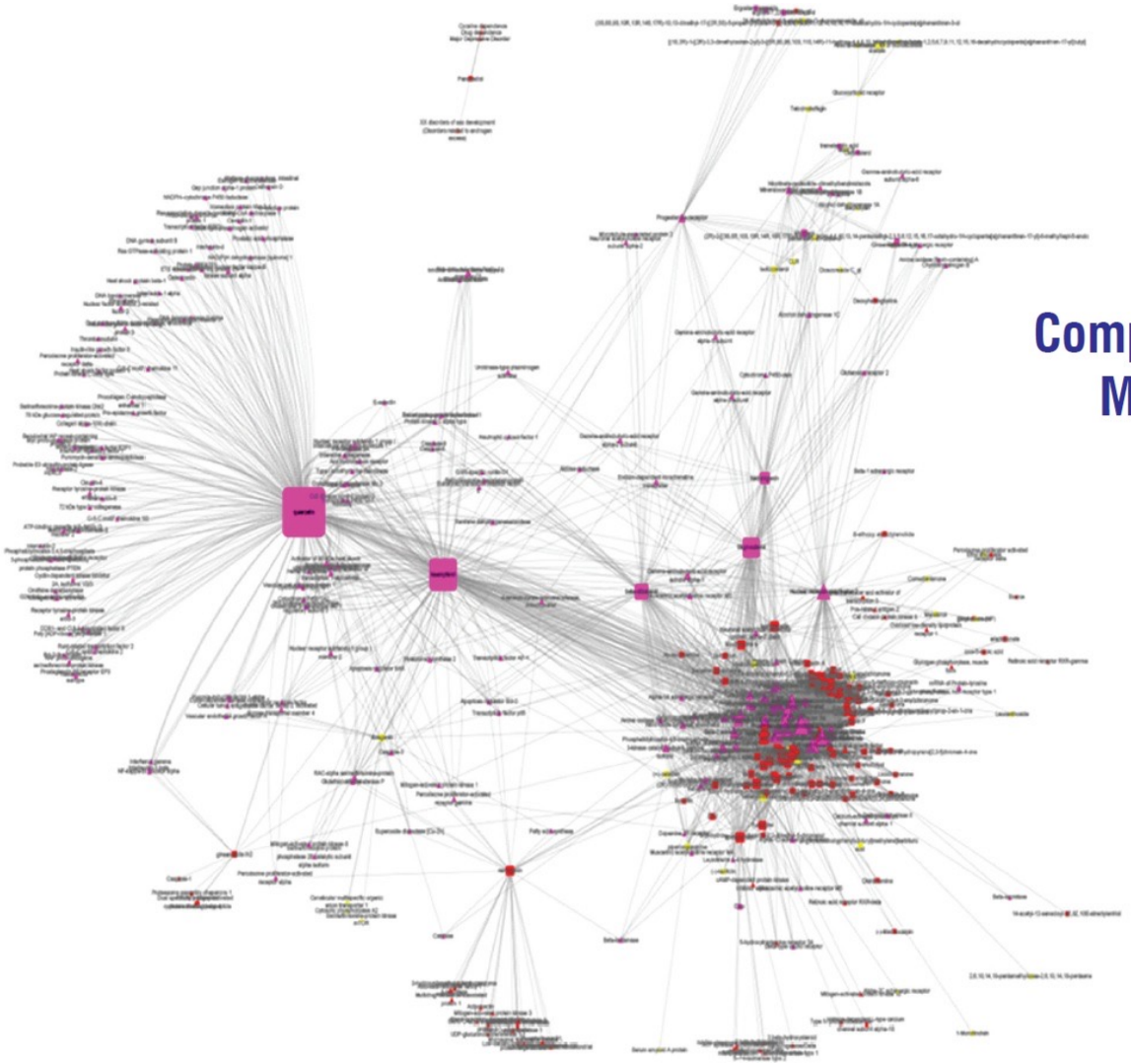
Xiao-Yan Li[a], Meng-Die Yang[a], Xue-Qing Hu[a], Fei-Fei Cai[a], Xiao-Le Chen[a], Qi-Long Chen[a], Shi-Bing Su[a]
[a]Research Center for Traditional Chinese Medicine Complexity System, Shanghai University of Traditional Chinese Medicine, Shanghai, Republic of China

Bu-Shen-Jian-Pi(補腎健脾方) = Liu-Wei-Di-Huang(六味地黃湯) + Si-Jun-Zi(四君子湯)

➡ 143 compounds, 275 targets

- Inflammation, Cancer, Alzheimer’s, Asthma
- Tumor-related targets concentrated in P13K/Akt and MAPK/ERK signaling pathways

Disease - ‘Zheng’ and Network Pharmacology (World Journal of TCM)



Compound-Target-Pathway Network Analysis and Effective Mechanisms Prediction of Bu-Shen-Jian-Pi Formula

Component

Target

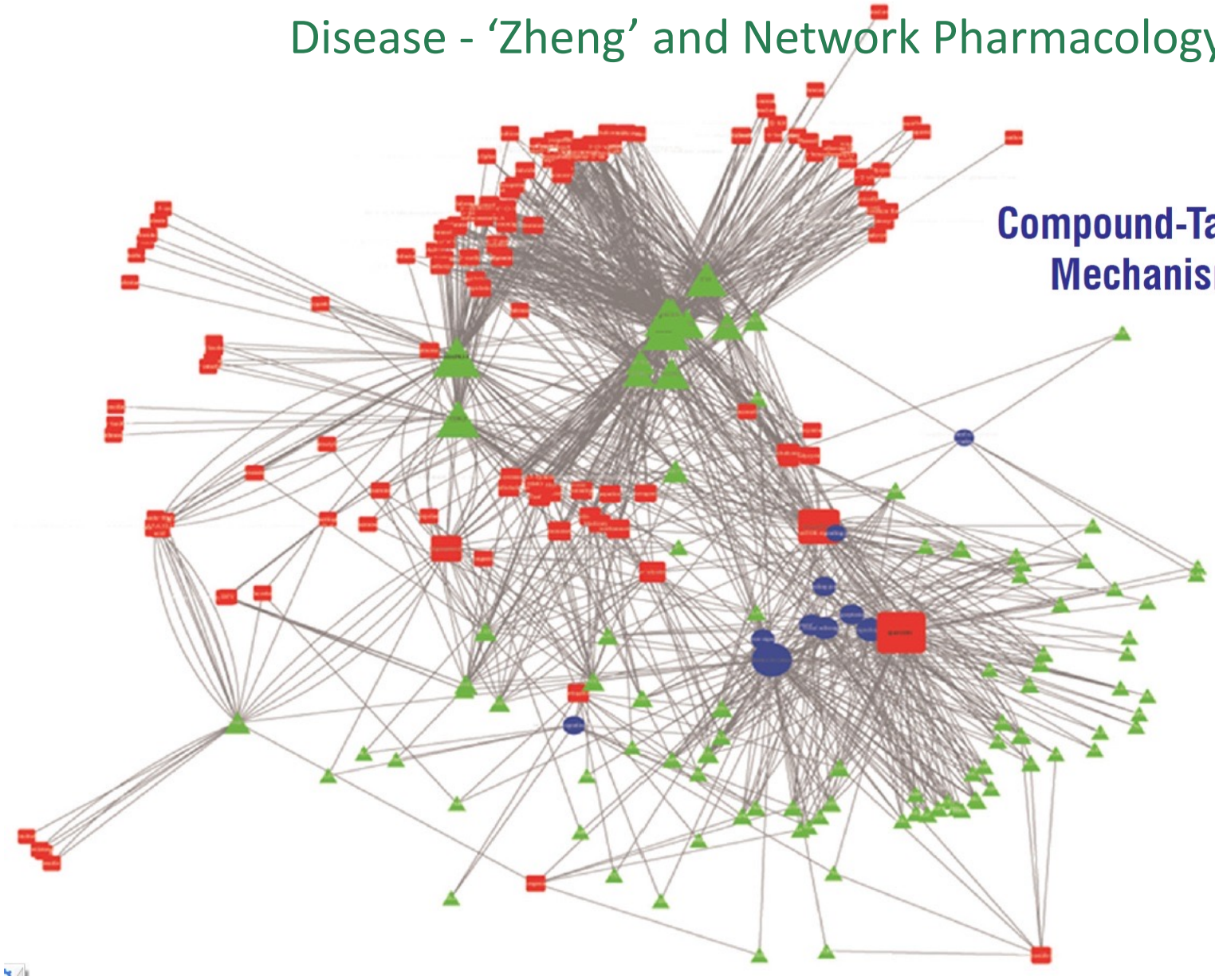
SJZ

LWDH

SJZ + LWDH

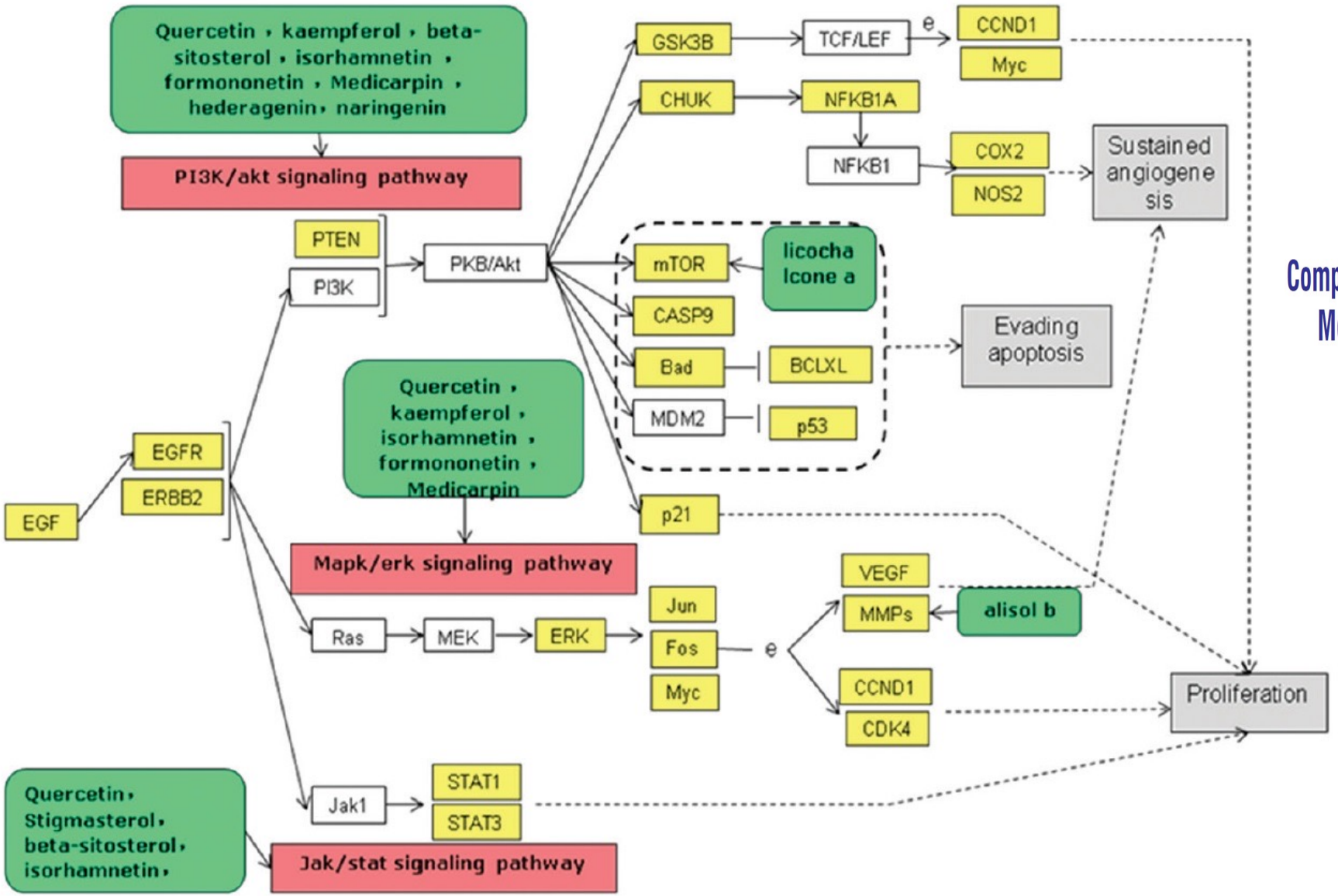
Square=component, triangle=target, Red= SJZ, yellow=LWDH, Rose red=SJZ+LWDH

Disease - ‘Zheng’ and Network Pharmacology (World Journal of TCM)



BSJP: red square=component, green triangle=target, blue circle= tumor related

Disease - 'Zheng' and Network Pharmacology (World Journal of TCM)



Compound-Target-Pathway Network Analysis and Effective Mechanisms Prediction of Bu-Shen-Jian-Pi Formula

- Compound
- Target
- Pathway
- Effect

BSJP: yellow box=target, red box=pathway, green box= key compound, gray box= effect

Disease - 'Zheng' and Network Pharmacology (World Journal of TCM)

Original Article

Compound-Target-Pathway Network Analysis and Effective Mechanisms Prediction of Bu-Shen-Jian-Pi Formula

Xiao-Yan Li[a], Meng-Die Yang[a], Xue-Qing Hu[a], Fei-Fei Cai[a], Xiao-Le Chen[a], Qi-Long Chen[a], Shi-Bing Su[a]

[a]Research Center for Traditional Chinese Medicine Complexity System, Shanghai University of Traditional Chinese Medicine, Shanghai, Republic of China

Table 1: Comparisons of predicted components, targets, GOs, and pathways of Bu-Shen-Jian-Pi formula, Liu-Wei-Di-Huang decoction, and Si-Jun-Zi decoction

Formula	Herbs	Components	Targets	GOs	Pathways
BSJPF	*Radix et Rhizoma Ginseng, R. Atractylodis Macrocephalae, Poria, Radix et Rhizoma Glycyrrhizae, Radix Rehmanniae Preparata, R. Dioscoreae, F. Corni, R. Alismatis,* and *C. Moutan*	143	265	1001	59
LWDHD	*Radix Rehmanniae Preparata, R. Dioscoreae, F. Corni, R. Alismatis, Poria,* and *C. Moutan*	29	7	1016	56
SJZD	Radix et Rhizoma Ginseng, R. Atractylodis Macrocephalae, Poria, and Gancao	101	44	89	6
Intersection of LWDHD and SJZD	*Poria*	13	214	75	3

BSJPF: Bu-Shen-Jian-Pi Formula, LWDHD: Liu-Wei-Di-Huang decoction, SJZD; Si-Jun-Zi decoction

Good Practice, Regulations & Scientific Innovation

1. Good Practice in Traditional Chinese Medicine (GPTCM)
2. Pharmacological Regulations and Vigilance
3. Disease - ‘Zheng’ and Network Pharmacology
4. Old Formulae for Major Disease Burden

Old Formulae for Major Disease Burden

Original Article

Traditional Chinese Medicine Based on *Zheng* Differentiation versus Angiotensin Receptor Blocker/Angiotensin-converting Enzyme Antagonist in Efficacy of Treating Diabetic Kidney Disease: A Meta-analysis of Randomized Clinical Trials

Wei-Jun Huang[a], Tao Yang[b], Chuan-Jiang Liu[b], Yong-Hua Xiao[b], Qiang Fu[b], Qing Gong[b], Hua Zhang[b], Fan Shao[b], Hong Yue[b], Shi-Dong Wang[b], Jin-Xi Zhao[b]
[a]Key Laboratory of Chin

In vitro, in vivo and clinical studies on diabetic kidney, diabetic foot ulcer and skeletal muscle insulin resistance

Original Article

Effect of Yinqi Ointment on Wound Morphology and Growth Factor in Treating Diabetic Foot Ulcer

Ya-Li Liu[a], You-Shan Li[a], Yu-Qing Du[a], Shuang Dai[b]
Departments of [a]Peripheral Vascular and [b]Orthopedics, Dongzhimen Hospital, Beijing U

Original Article

Effects of Ginsenoside Rb1 on Skeletal Muscle Insulin Resistance and Adenosine Monophosphate-activated Protein Kinase Signaling Pathway in Obese Mice

Dan-Dan Zhao[a], Ying Bai[a], Rui Wu[b], Fang-Fang Mo[a], Chen-Yue Liu[a], Ru-Yuan Zhu[a], Guang-Jian Jiang[a], Jia-Xian Liu[c], Dong-Wei Zhang[a], Si-Hua Gao[a]
[a]School of Chinese Medicine, Beijing University of Chinese Medicine, [b]Department of Endocrinology, South Area of Guang'anmen Hospital, China Academy of Chinese Medical Sciences, Beijing, China, [c]Leonard Davis School of Gerontology, University of Southern California, Los Angeles, CA, USA

Old Formulae for Major Disease Burden

Review Article

Effects of the Clearing the Lung and Dissipating Phlegm Method in the Treatment of Acute Exacerbation of Chronic Obstructive Pulmonary Disease: A Systematic Review and Meta-Analysis

TCM pattern-directed 宣肺化痰 treatment for Chronic Obstructive Pulmonary Disease

Tao Zhang[a], Y
[a]Department of Traditional Chinese Medicine, First Clini
[b]Department of Pulmonary Diseases, Sh

Original Article

Effects of Peiyuan Tongnao Capsule on Working Memory and the Expression of Glutamic Acid and Receptor in Hippocampal Area in Rats with Cerebral Ischemia

Jing Bai[a], Ying Gao[a,b], Yong-Hong Gao[b], Wang Li[a]
[a]Department of Neurology, Dongzhimen Hospital, Beijing University of Chinese Medicin
Beijing University of Chinese Medicine, Bei

Cerebral ischemia:

1. 培元通腦膠囊 on rat memory
2. Screening for antioxidants and Q markers of 宣腦心丸

Original Article

Integrated Network Pharmacology and Antioxidant Activity-Guided Screen System to Exploring Antioxidants and Quality Markers of Shunaoxin Pills against Chronic Cerebral Ischemia

Nian-Wei Chang[a], Dan-Dan Cheng[a], Jia-Nan Ni[a], Ying-Ying Guo[a], Guang-Cui Chu[a], Unchol Kim[b,c], Min Jiang[b], Gang Bai[b]
[a]Graduate School, Tianjin University of Traditional Chinese Medicine, [b]College of Pharmacy, State Key Laboratory of Medicinal Chemical Biology, Tianjin Key Laboratory of Molecular Drug Research, Nankai University, Tianjin, People's Republic of China, [c]Department of Genetic Engineering, State Academy of Sciences, Pyongyang, Democratic People's Republic of Korea

Old Formulae for Major Disease Burden

Original Article

Exploring the Pathways and Targets of Shexiang Baoxin Pill for Coronary Heart Disease through a Network Pharmacology Approach

Shou-De Zhang[a,c], Zhan-Hai Su[a], Rui-Hui Liu[b], Yan-Yan Diao[c], Shi-Liang Li[c], Ya-Ping-Hua[d], Hong-Lin Li[c], Wei-Dong Zhang[b,c]

[a]State Key Laboratory of Plateau Ecology and Agriculture, Qing
Medical University, [c]Shanghai Key Laboratory of New Drug
[d]Department of Clinical Science 2

Explore pathway and target of 麝香補心丸 for CHD

Original Article

Study on the Biological Basis of Hypertension and Syndrome with Liver-Fire Hyperactivity Based on Data Mining Technology

Xue-Ling Ma[a], Xing Zhai[b], Jing-Wei Liu[c], Xiao-Xing Xue[d], Shu-Zhen Guo[c], Hua Xie[c], Jian-Xin Chen[c], Hui-Hui Zhao[c], Wei Wang[c]

[a]School of Nursing, Beijing University of Chinese Medicine (B
University of Chinese Medicine (BUCM), [d]

Data mining for biological basis of hypertension & 肝火亢盛

Original Article

A Network Pharmacology Approach to Decipher the Mechanisms of Anti-depression of Xiaoyaosan Formula

Yao Gao[a,b], Li Gao[a,b], Jun-Sheng Tian[a,b], Xue-Mei Qin[a,b], Xiang Zhang[c]

[a]Modern Research Center for Traditional Chinese Medicine, [b]Shanxi Key Laboratory of Active Constituents Research and Utilization of TCM, Shanxi University, Taiyuan 030006, China, [c]Departments of Chemistry, University of Louisville, Louisville, KY 40292, USA

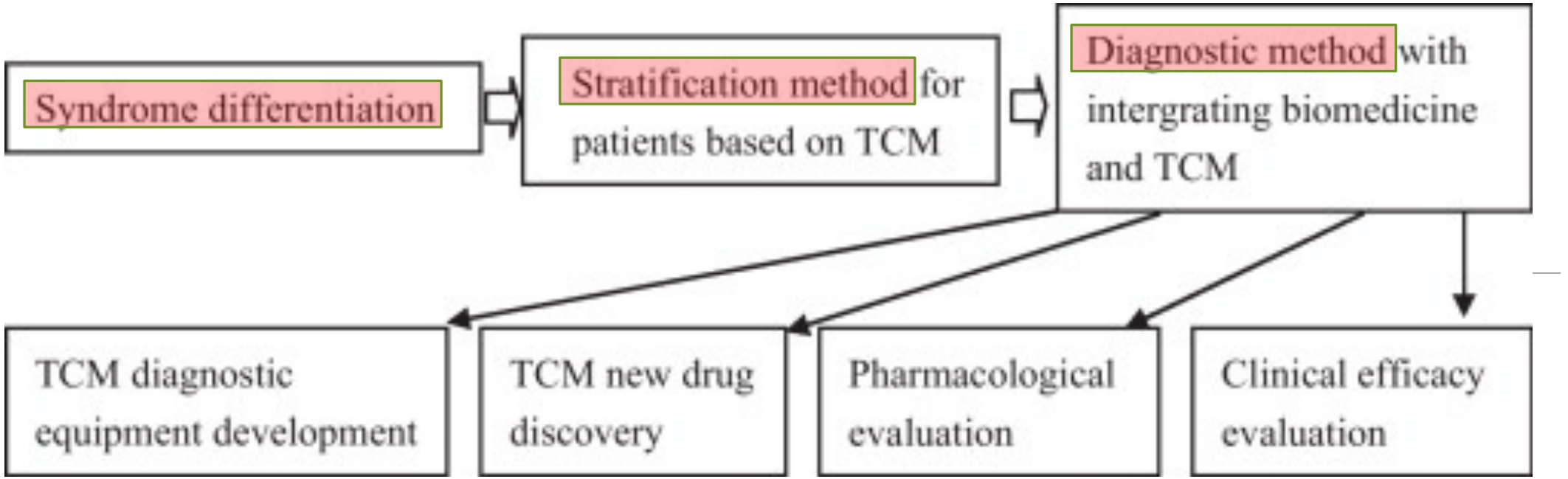
Network analysis of 逍遙散 for depression

Old Formulae for Major Disease Burden

Syndrome differentiation in modern research of traditional Chinese medicine.

中药是中医理论指导下使用的药物

Miao Jiang, Cheng Lu, Chi Zhang, Jing Yang, Yong Tan, Aiping Lu, Kelvin Chan.



J Ethnopharmacol 2012;140:634–42 **Cited 108 times**

Science Press

Journal homepage:
www.jcimjournal.com/jim
www.elsevier.com/locate/issn/20954964
Available also online at www.sciencedirect.com.

Old Formulae for Major Disease Burden

• Research Article

Identification and classification of traditional Chinese medicine syndrome types among senior patients with vascular mild cognitive impairment using latent tree analysis

Chen Fu[1], Nevin Lianwen Zhang[2], Bao-xin Chen[1], Zhou Rong Chen[2], Xiang Lan Jin[1], Rong-juan Guo[1], Zhi-gang Chen[1], Yun-ling Zhang[1]

1. Department of Neurology, Dongfang Hospital, Beijing University of Chinese Medicine, Beijing 100078, China
2. Department of Computer Science and Engineering, The Hong Kong University of Science and Technology, Hong Kong, China

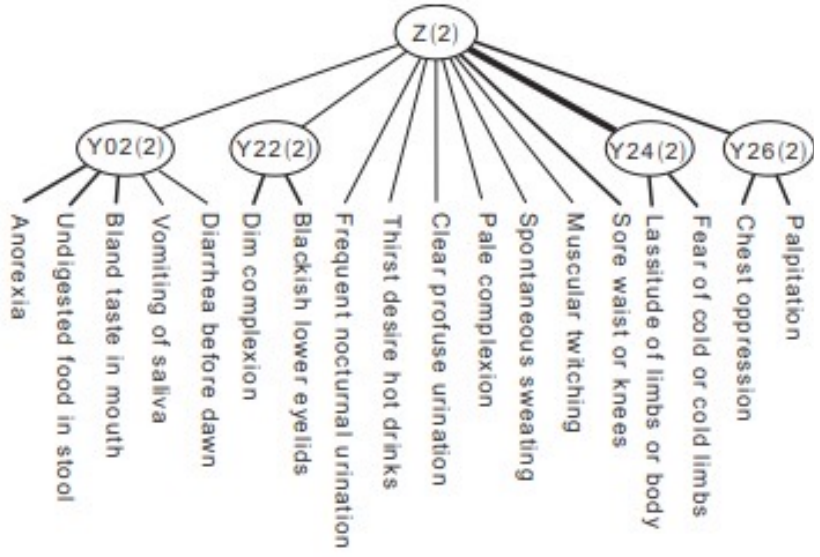


Figure 1 Joint clustering model for Yang deficiency

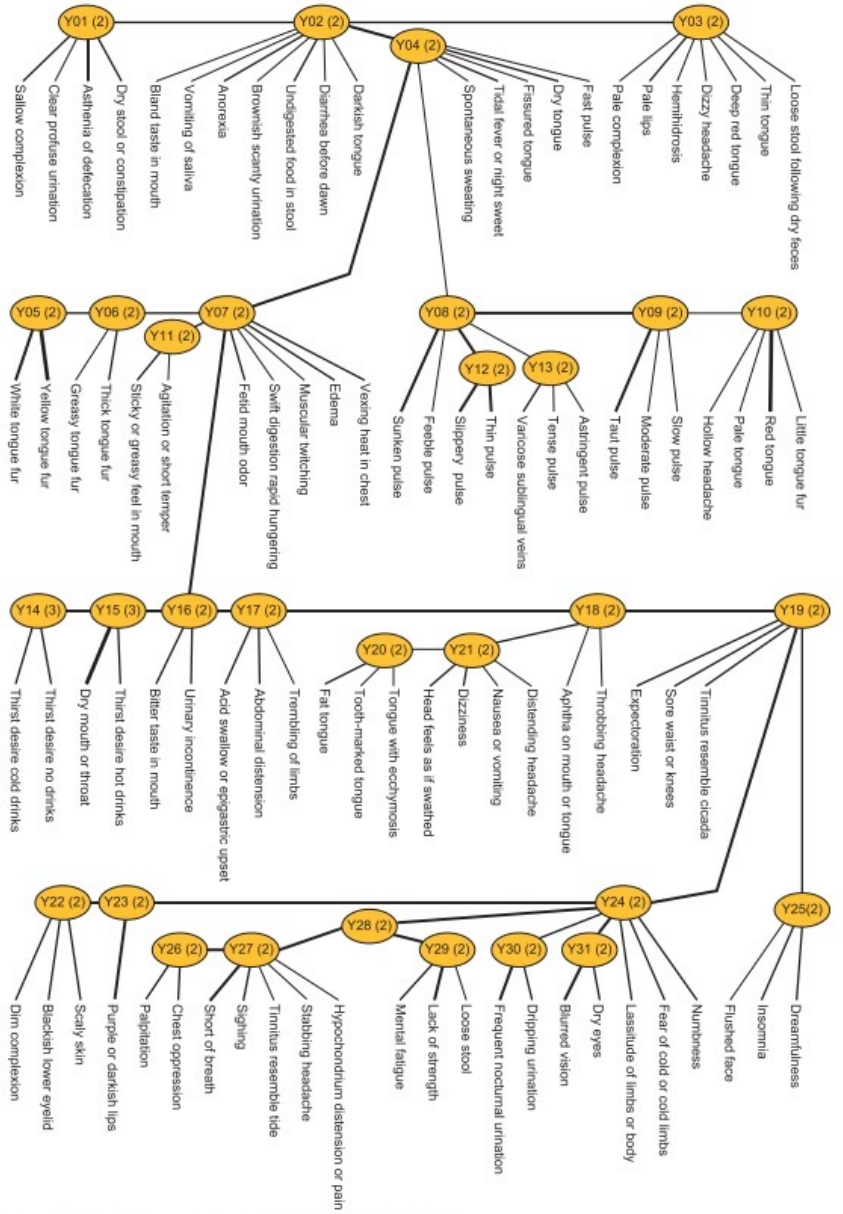
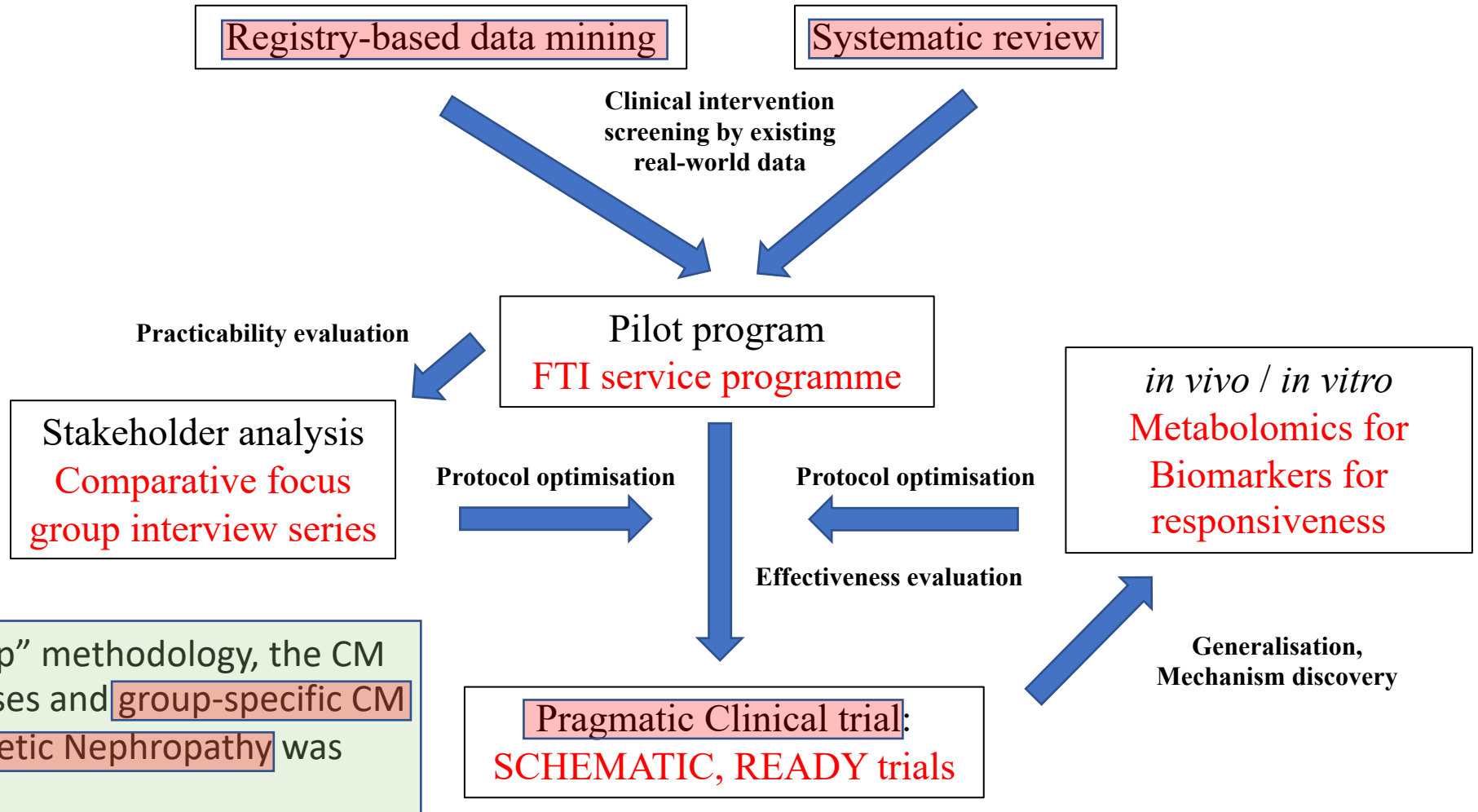


Figure 3 Structure of the latent tree model obtained on the VMCI data
The variables labeled with English phrases are symptom variables, while the *Y*-variables are latent variables. The integer next to a latent variable is the number of its possible values. VMCI: vascular mild cognitive impairment.

History taking (問診) for TCM syndrome diagnosis (辨證) using clustering model for vascular mild cognitive impairment (MCI)

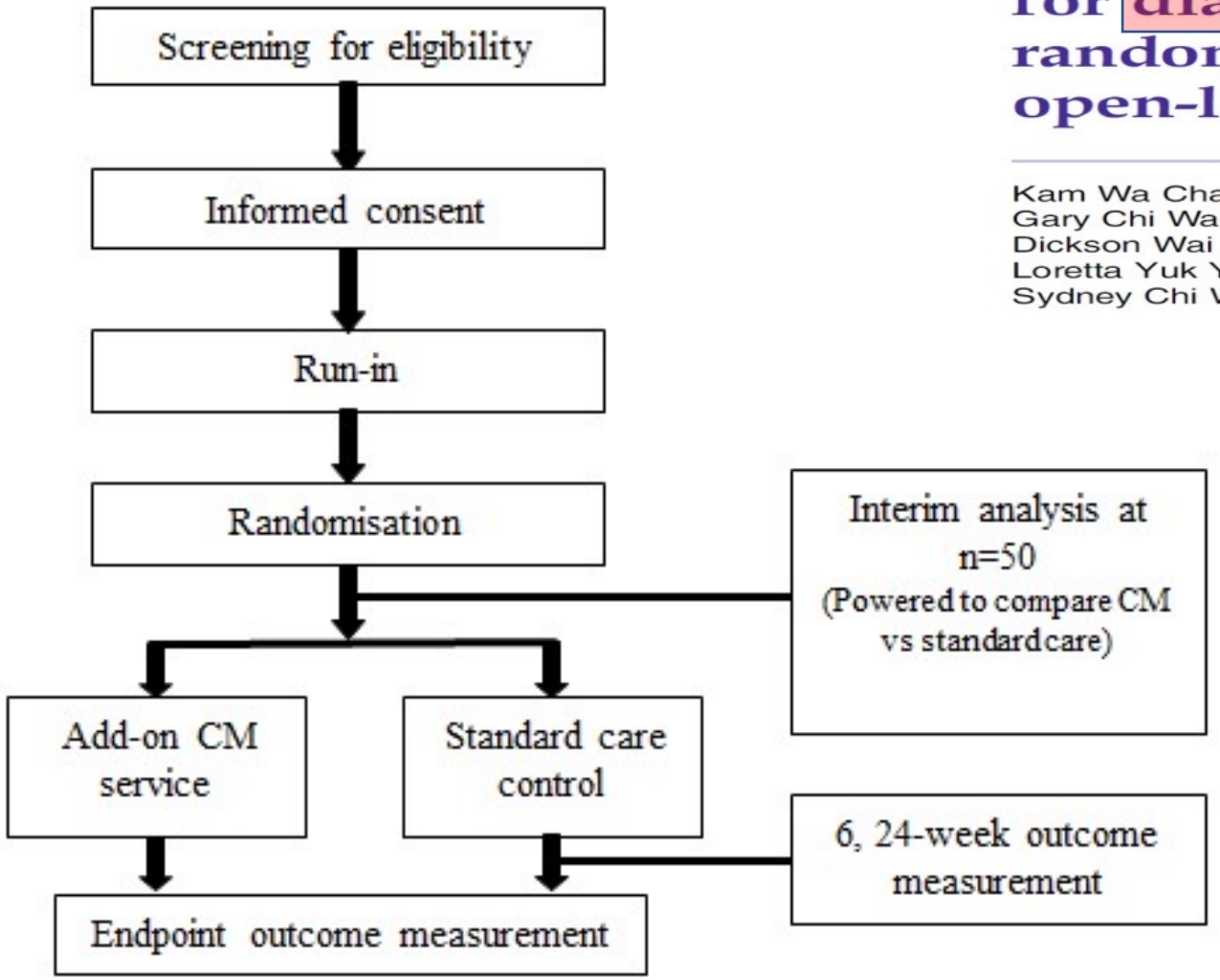
Old Formulae for Major Disease Burden



Using “focus group” methodology, the CM syndrome diagnoses and group-specific CM formulae for Diabetic Nephropathy was determined.
A pragmatic clinical trial is being conducted using this semi-individualized therapy .

Chan KW et al. 2019

Old Formulae for Major Disease Burden



Open Access Protocol

BMJ Open

Semi-individualised Chinese medicine treatment as an adjuvant management for diabetic nephropathy: a pilot add-on, randomised, controlled, multicentre, open-label pragmatic clinical trial

Kam Wa Chan,[1] Tai Pang Ip,[2] Alfred Siu Kei Kwong,[3] Sing Leung Lui,[2] Gary Chi Wang Chan,[4] Benjamin John Cowling,[5] Wai Han Yiu,[1] Dickson Wai Leong Wong,[1] Yang Liu,[1] Yibin Feng,[6] Kathryn Choon Beng Tan,[7] Loretta Yuk Yee Chan,[1] Joseph Chi Kam Leung,[1] Kar Neng Lai,[1] Sydney Chi Wai Tang[1]

AIM

To evaluate the effect of a 48-week add-on semi-individualized CM treatment program on T2DM patients with stages 2 to 3 CKD and macroalbuminuria

Primary outcomes: eGFR, UACR
Secondary Outcomes: HbA1c, blood pressure, adverse event rates

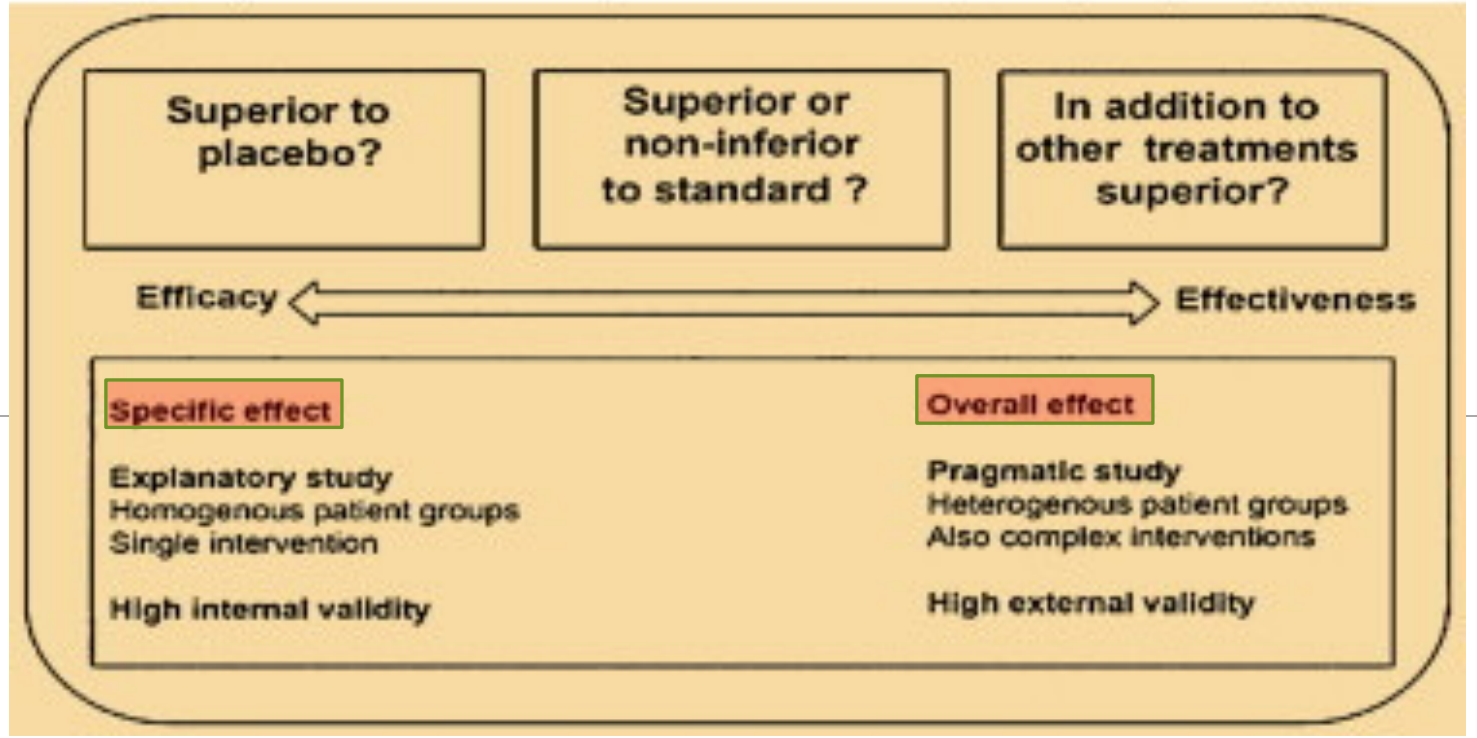
Chan KW et al. 2017

Guidelines for randomised controlled trials investigating Chinese herbal medicine.

中药临床研究规范

Andrew Flower, Claudia Witt, Jian Ping Liu, Gudrun Ulrich-Merzenich, He Yu, George Lewith.

The relationship between the research question and the corresponding study design (Witt 2009)



J Ethnopharmacol 2012;140:550–54 60 citations

Old Formulae for Major Disease Burden

Comparison of effectiveness and safety between granules and decoction of Chinese herbal medicine: A systematic review of randomized clinical trials
中药颗粒剂与传统汤剂的比较研究

Hui Luo, Qing Li, Andrew Flower, George Lewith, Jianping Liu

Due to the poor methodological quality of most of the included trials, it is not possible to reach a definitive conclusion whether both Chinese herbal medicine granules and decoctions have the same degree of effectiveness and safety in clinical practice. Standardization of granules and further pharmacological, toxicological and clinical studies are needed to demonstrate the equivalence with decoctions.

Poor methodology, no conclusion, needs standardization

J Ethnopharmacol 2012;140:555–567 **Cited >30 times**

Old Formulae for Major Disease Burden

RESEARCH AND REPORTING METHODS Annals of Internal Medicine

CONSORT Extension for Chinese Herbal Medicine Formulas 2017: Recommendations, Explanation, and Elaboration

Chung-wah Cheng, MPH; Tai-xiang Wu, MPH; Hong-cai Shang, MD, PhD; You-ping Li, MPH; Douglas G. Altman, PhD; David Moher, PhD; and Zhao-xiang Bian, MD, PhD; for the CONSORT-CHM Formulas 2017 Group*

中藥複方臨床隨機對照試驗報告規範2017：CONSORT聲明的擴展、說明與詳述

- Introduced TCM pattern, features of CHM formulae
- New checklist sub-item, keywords for indexing and searching
- Elaborated 7 checklists: Title & Abstract, Background & Objectives, Participants, Interventions, Outcomes, Generalizability, Interpretation
- Revised 'harm' specific to CHM formulae

Old Formulae for Major Disease Burden

SCIENTIFIC REPORTS

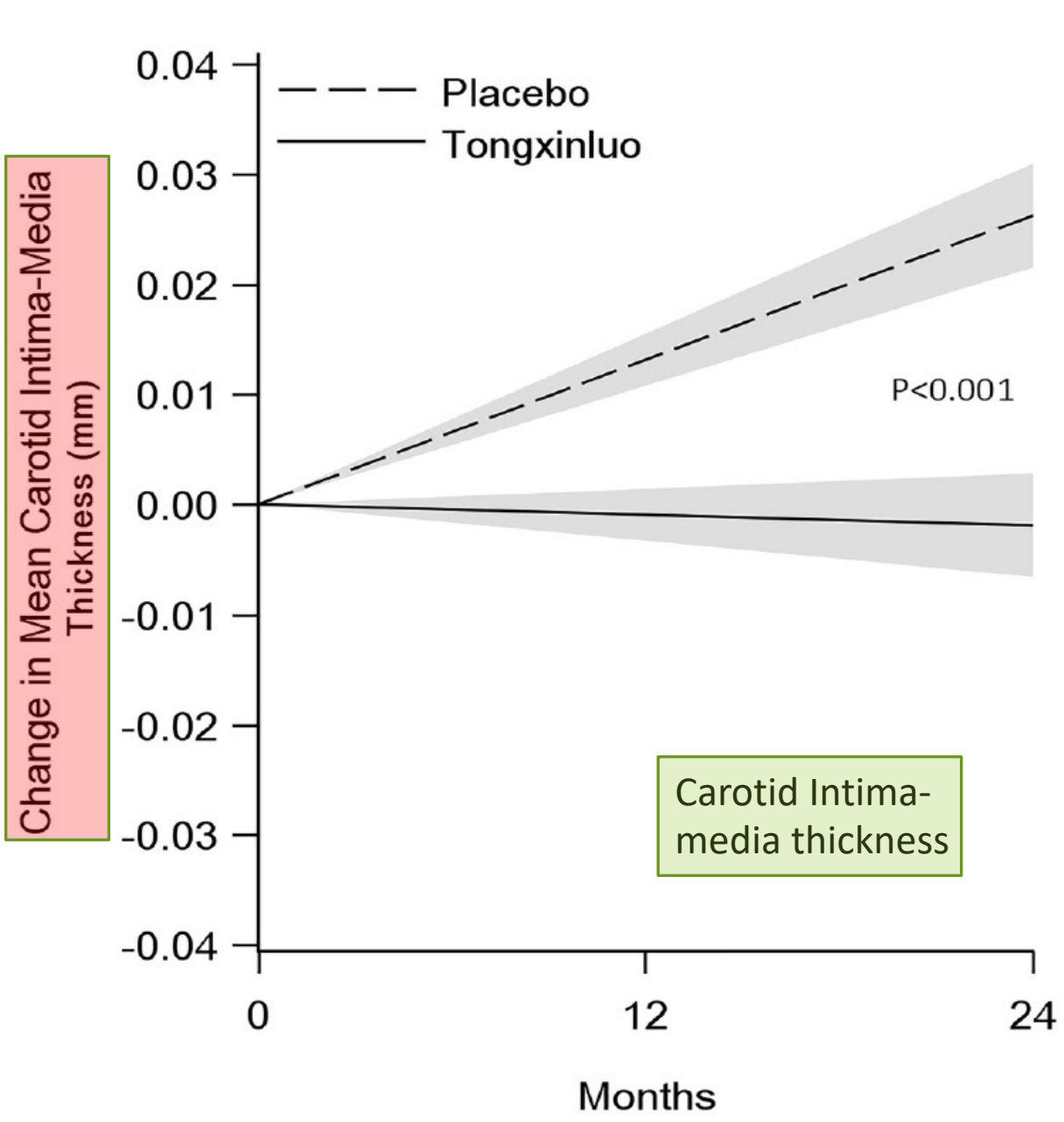
OPEN

Carotid artery plaque intervention with Tongxinluo capsule (CAPITAL): A multicenter randomized double-blind parallel-group placebo-controlled study

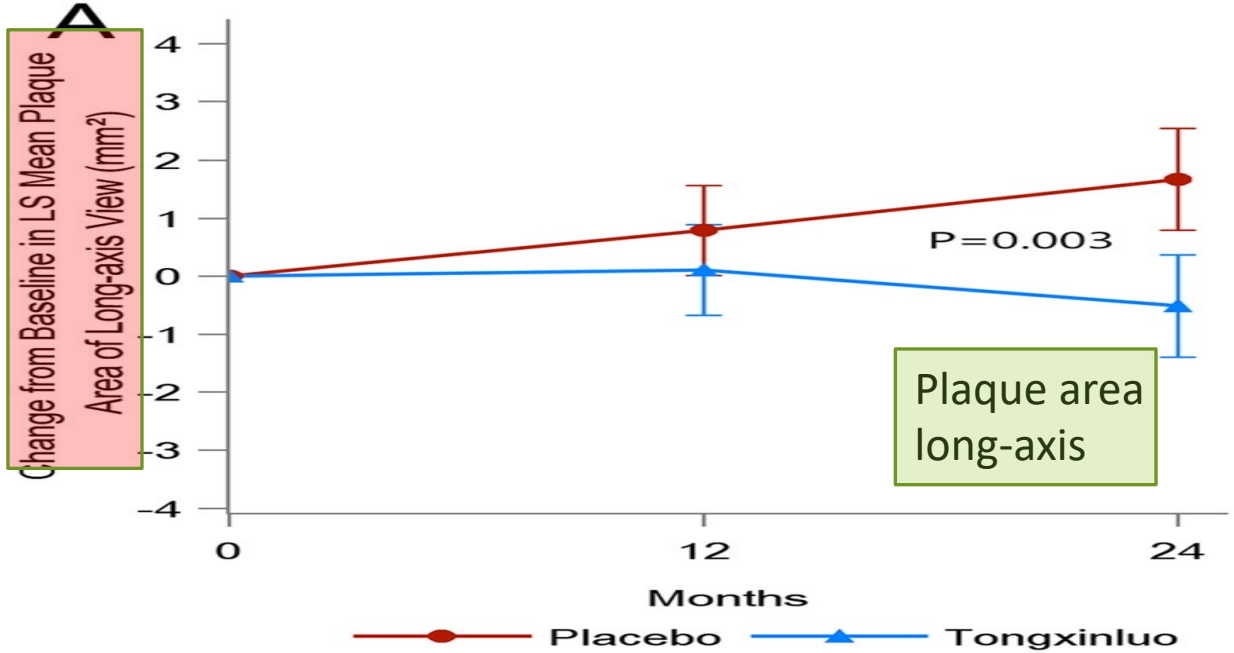
Received: 10 March 2017
Accepted: 28 February 2019
Published online: 14 March 2019

- 3273 -> 1212 patients with carotid intima-media thickness (IMT) >/= 1.2mm
- Tongxinluo 6 capsules bd, over 24 months (499 completed) vs placebo (509 completed)
- Retarded progression of mean IMT, plague area & vascular remodeling index
- Significantly reduced 1st major cardiovascular events

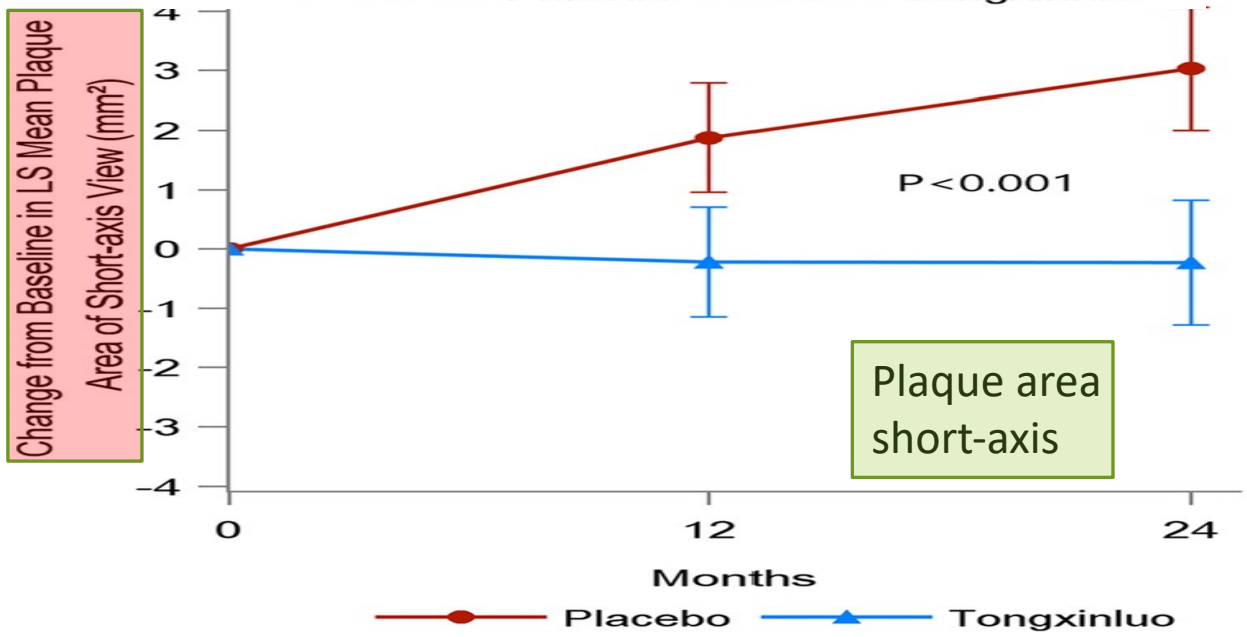
Old Formulae for Major Disease Burden



Carotid Intima-media thickness

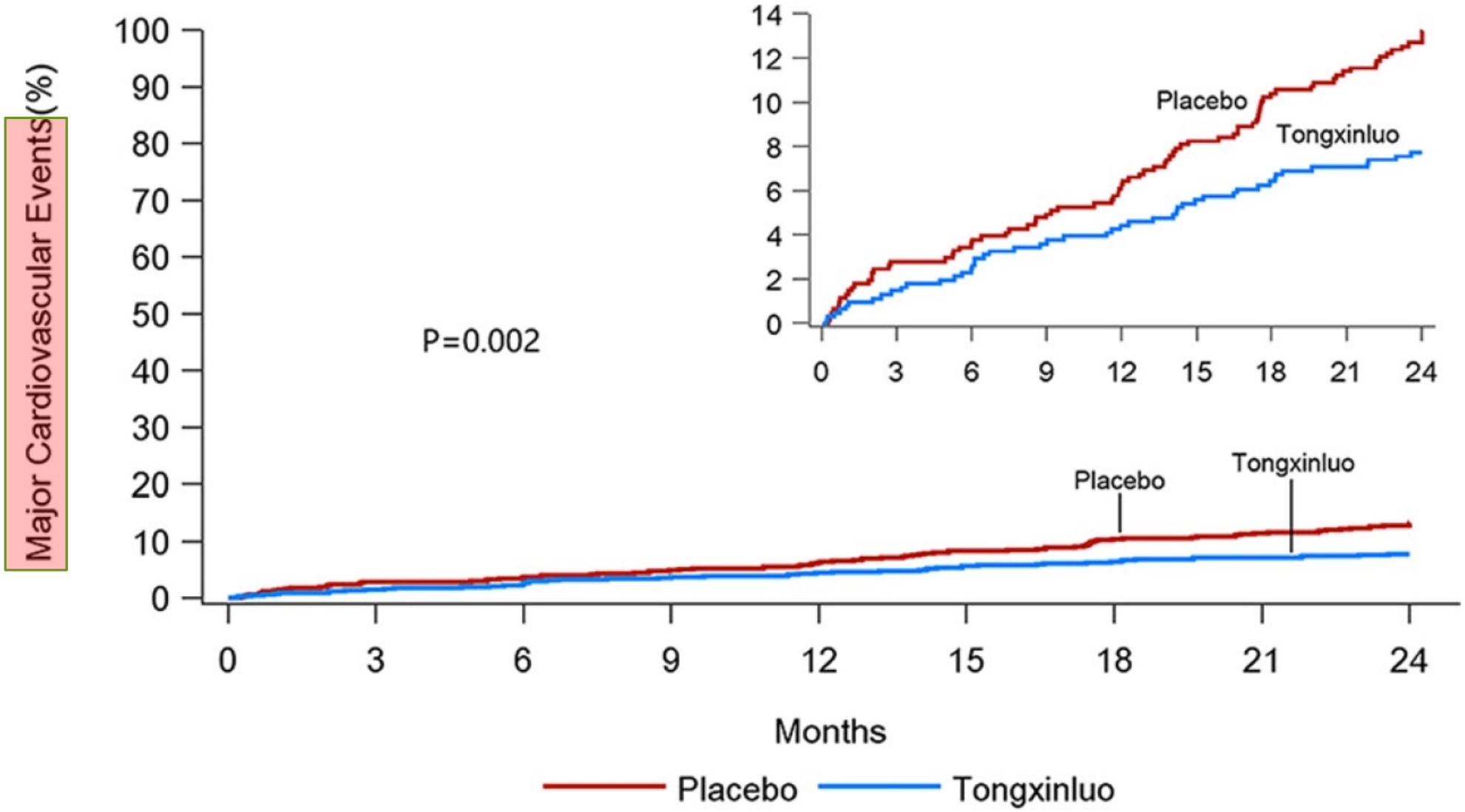


Plaque area long-axis



Plaque area short-axis

Old Formulae for Major Disease Burden



No.at Risk

Placebo 605	588	583	575	567	555	542	536	525
Tongxinluo 607	598	592	585	580	573	568	564	560

Old Formulae for Major Disease Burden

National Program for Modernization of TCM國家重點研究計劃“中醫藥現代化研究”
(Evidence evaluation & mechanistic effect demonstration study)
十種中成藥大品種和經典名方上市後治療重大疾病的循證評價和其效應機制的示範研究

Objectives:
- produce high level evidence
- develop evaluation methods by level/by category
- academic-led guideline development
- support decision by doctors, industry & government (medical insurance)

3 framework contents:

- demonstration research,
- research guidelines,
- technical methodology

4 major disease burden:
- cardio-vascular,
- cerebral vascular,
- cancer & syndromes,
- infectious diseases

10 Old Formulae: 3 classical formulae, 7 major products on the market

Acknowledgement

1. Good Practice Traditional Chinese Medicine Research Association (GPTCMRA)
2. International Regulatory Agencies
3. 《Ethnopharmacology》,《World Journal of Traditional Chinese Medicine》
4. Dr Christine Leon, Royal Botanic Garden Kew; Anastasiya Timoshyna, TRAFFIC
5. Professional leaders, academics, researchers & funders

The 7th Annual Meeting of Good Practice in Traditional Chinese Medicine Research Association (GP-TCM RA)

Hosted by

National Development Institute of Korean Medicine (NIKOM) & Daegu Haany University, Daegu City, South Korea

9-10 July 2019

For more details, please refer to http://www.gp-tcm.org/