

中医药的最新临床研究及发展趋势

Latest R&D Trends in Chinese Medicine

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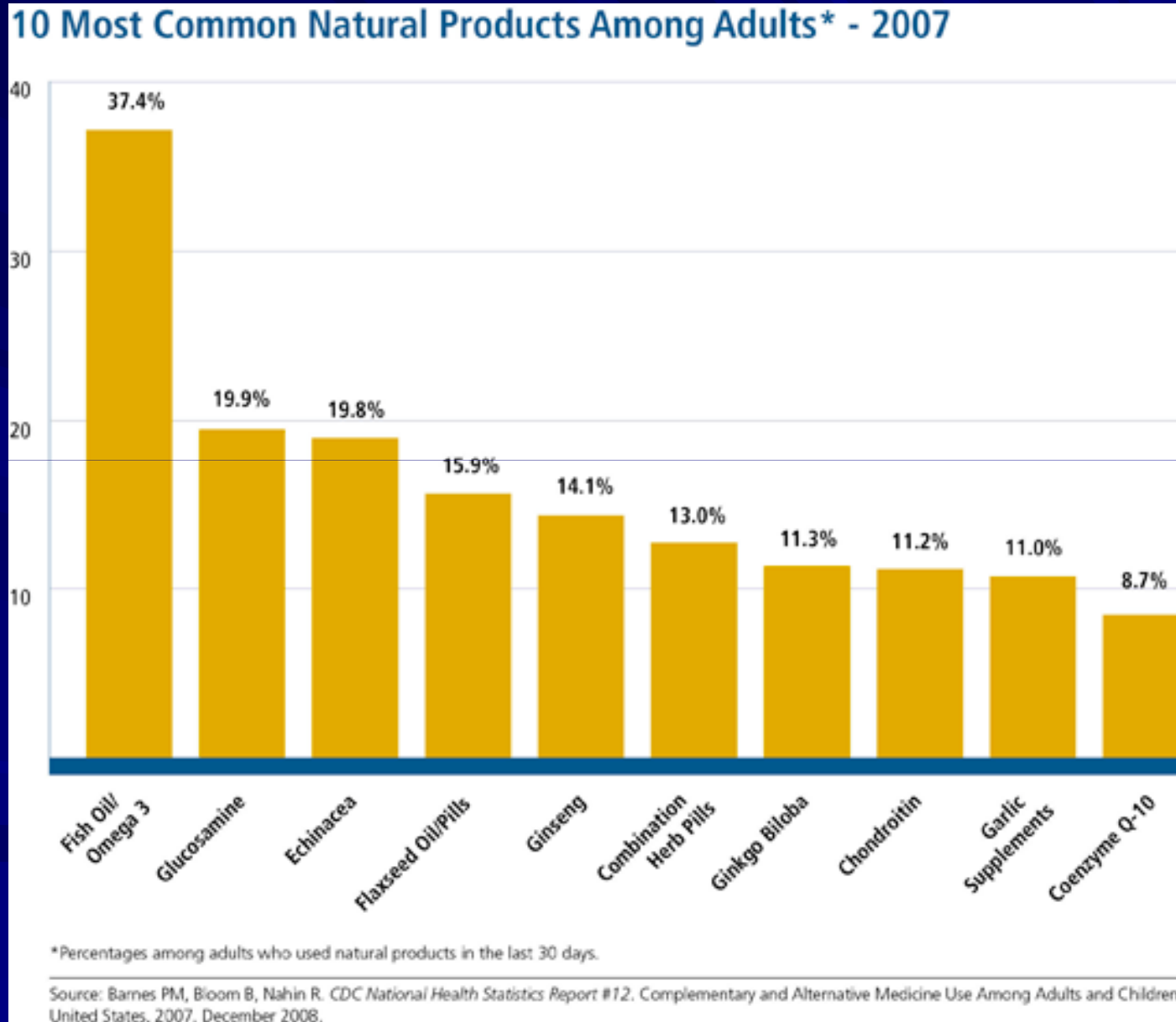
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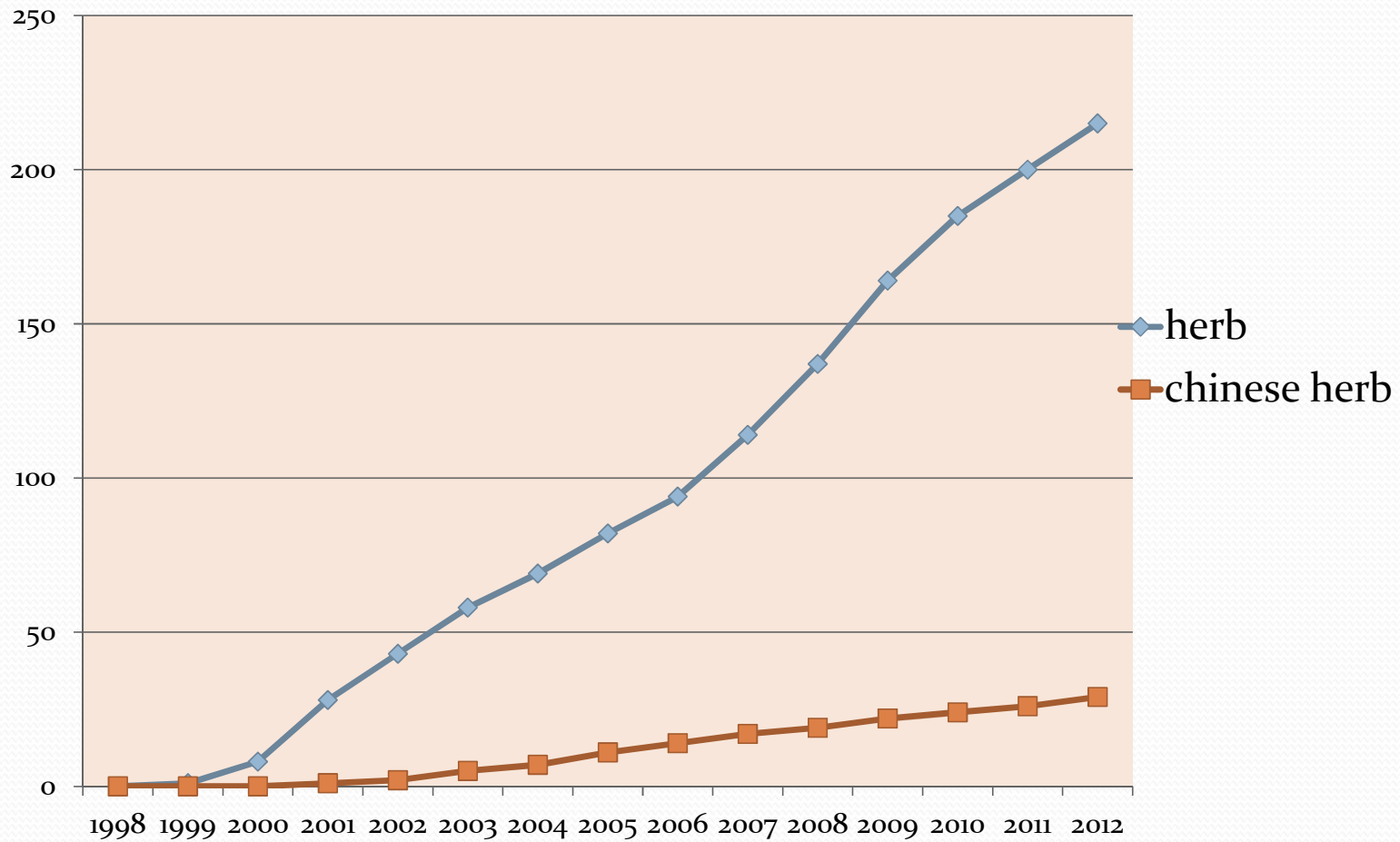
Hong Kong, China, September 5, 2013

十种在美国最常用的天然产品



在西方，中医药，相较于草药，研究经费的支持力度明显不足
In the West, CHM trials are rarely funded

NIH Funded Projects, Cumulative Totals



对科克伦补充医学注册的随机对照临床试验的分析

Bibliometric and content analysis of the Cochrane Complementary Medicine Field Specialized Register of Controlled Trials.

- Wieland et al., [Syst Rev.](#) 2013 Jul 4;2:51.

CAM Field Register increases 注册数的增加:

2006: < 5,000 controlled trial citations

2011: 44,840 citations.

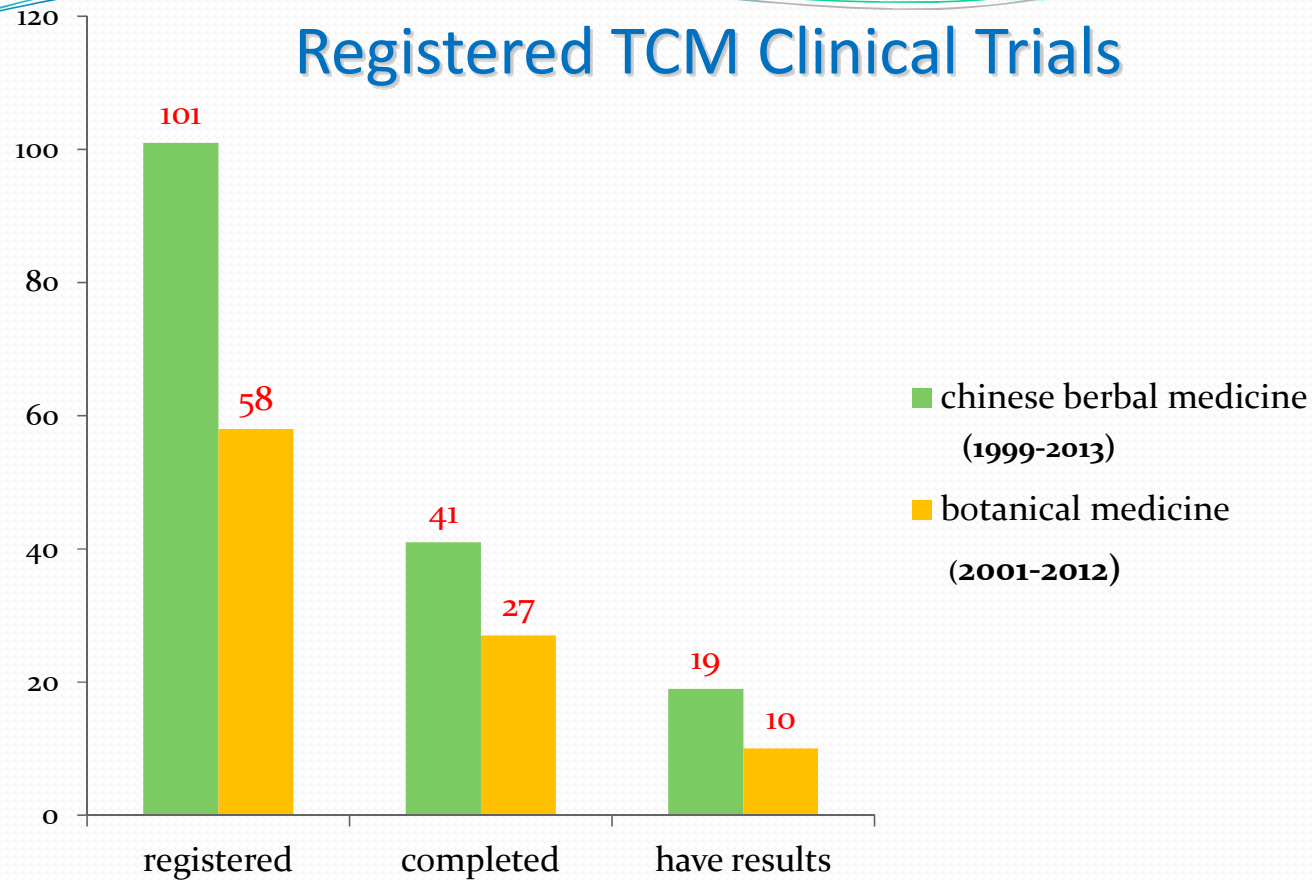
Reports in English: 71% 英语报道的71%

The next most common language was Chinese 中文: 23%

The most common CAM intervention type was supplements such as glucosamine, fish oil (34%), 最多的RCTs是补充剂 (34%)

The second most common CAM intervention was Chinese herbal medicines such as *Astragalus membranaceus* 黄芪, *Schisandra chinensis* 五味子 (27%). 中药的RCTs占27%

在NIH注册的草药/中药的临床试验



ClinicalTrials.gov

A service of the U.S. National Institutes of Health

几乎所有大型临床试验都显示补充剂无临床疗效

Most Large Clinical Trials on individual Supplements Have Failed

-- Briggs & Killen, JAMA , Aug.21.2013

These include:

St John's wort for major depression 抑郁症

glucosamine and chondroitin sulfate for knee osteoarthritis 关节炎

silymarin for chronic liver disease 慢性肝病

saw palmetto for benign prostatic hyperplasia 前列腺肥大

ginkgo for early cognitive decline 认知减退

vitamin E and selenium to prevent prostate cancer 前列腺癌

The results of these large studies failed to confirm benefits seen in earlier preliminary studies. 这些结果与他们的前期预初试验不一致

系统评价显示几乎所有中医药的临床试验结果都为阳性 All Clinical Studies Conducted in China on Chinese Herbal Medicine (CHM) Have Been Positive

A meta-analysis suggested that modified Chaihu Shugan powder alone or in combination with prokinetic drugs might be more effective than prokinetic drugs alone in improving symptoms of functional dyspepsia.

(22 RCTs) Meta分析显示柴胡疏肝散或加上西药要比单独西药对治疗功能性消化不良有效
-- Yang et al., eCAM, April. 2013

Tianshu capsules were more efficacious and had fewer adverse effects than conventional medication in the treatment of migraine **(10 RCTs)**.

Tianshu胶囊对治疗偏头痛有效且少不良反应 -- Xia et al., JTCM, Feb., 2013

Using Duhuoji sheng Tang alone or combined with other therapies can effectively improve pain ... and other clinical symptoms of intervertebral lumbar disc prolapse. **(31 RCTs)**

单独使用独活寄生汤或结合其他疗法治疗腰椎间盘突出是有效的

-- Ma et al., JTCM, April, 2013

A banxiaxixin decoction can restore gastric emptying rate and improve diabetic gastrointestinal symptoms. **(16 RCTs)**

半夏泻心汤对糖尿病胃肠道症状有改善作用

-- Tian et al., eCAM, May 2013

但是这些RCTs的研究方法质量普遍较低

The Methodological Quality of Most CHM Trials Is Low

Because of poor methodological quality, all the included trials were at high risk of bias. 但这些试验（柴胡疏肝散）都存在低质量，高偏差风险的问题
-- Yang et al., eCAM, April. 2013¹⁰

There were no large-scale, multi-centered RCTs, and few of the trials were blinded.

这些试验（Tianshu胶囊）少有大样本，多中心，并少有实行盲法
-- Xia et al., JTCM, Feb., 2013

Due to the poor methodological quality of the articles, no recommendations can be made. 由于试验（独活寄生汤）方法质量低，我们不能推荐该药
-- Ma et al., JTCM, April, 2013

However, the methodological quality of included studies is low....
但是，这些临床试验（半夏泻心汤）的研究方法质量很低。。。.
-- Tian et al., eCAM, May 2013

中医在西方发展的挑战和障碍

**Challenges and Barriers to Promoting TCM in the
West**

中西方文化差异

Cultural Differences Between West and East

- 中医理论不易被西方医学界理解和接受
TCM theory is not easily understood or accepted by the Western medical community.
- 中医理论如阴阳五行更象哲学甚至宗教，所以难以用科学检验
TCM theories such as Yin-Yang and five-element theory are more like philosophy or even religion and can not be scientifically tested.

对中药安全性的担忧

Safety Concerns

- 对中药制品的质量控制如重金属污染及掺西药假药的担心
Concerns about herbal product quality control, heavy metal contamination, and adulteration
- 媒体报道的某些中药的副作用及毒性
Media reports of adverse effects and the toxicity of certain herbs

对中医药有效性及质量控制的担忧

Concerns about Efficacy and Quality Control

- 中医药科研成果鲜有发表于西方前沿杂志
Lack of scientific data on Chinese herbal medicine in Western peer-reviewed journals
- **FDA**批准上市的草药产品很少
Lack of FDA-approved herbal medicines
- 由于缺少科研数据，**FDA**把中草药归类为食品补充剂，不能标明治疗适应症
Because scientific evidence on Chinese herbs is lacking, the FDA classifies them as food supplements and no treatment indications can appear on the labels.

中医药临床试验缺乏完善的外部监督制度

CHM Clinical Trials Lack External Monitoring

在国内进行的中医药的临床试验都没建立独立的数据和安
全监察委员会（这在美国**NIH**资助的临床试验是必须有的）

Few if any CHM trials conducted in China have external Data and Safety Monitoring Boards (DSMB), which are required in all NIH-funded trials.

很少有临床试验获取美国或中国食品和药物管理局的临床
试验许可证

Few CHM trials conducted in China obtain Investigational New Drug (IND) status from the US Food and Drug Administration (FDA) or the CFDA.

以上的数据显示中西方在对中医药研究的动机和目的的不同

The Differences in CHM Research between East and West are due to Differing Motivations and Purposes

- a)** 在西方，人们以实用主义对草药或补充剂进行严谨的研究以真正了解这些产品的有效性，对何种疾病/症状有效，及其毒副作用。
In the West, people want supplements useful for symptom management. Thus researchers want to determine whether a supplement works.
- a)** 在中国，对中医药的研究更多的是为了证明它是有效的。所以对是否产生阳性结果更有兴趣，而往往忽略方法上的严谨。
In China, CHM research is more or less to defend a principle. Thus the researchers want to prove that CHM does work; they focus on final results, not on rigorous methodology to reach those results.

认识危机，面对挑战

Recognize the Crisis and Face the Challenges

1) 辨别西医与中医之间， 中医研究与中药研究之间的差异

Identify the differences between Western and Chinese Medicine and the concomitant research on Chinese medicine and Chinese herbs.

2) 建立评价中医的研究策略和方法

Set up research strategies and methodologies for evaluating TCM.

3) 利用近代发展的现代医学的研究方法如循证医学方法

Take advantage of recently developed Western medical research methodology and evidence-based medicine.

4) 避免西医西药研究的缺陷

Avoid the limitations of Western medical research.

辨别西医与中医的差异

Identify the differences between Western and Chinese Medicine

西医体系 Western Medicine	中医体系 Traditional Chinese Medicine
<i>Specify Disease</i> 注重疾病的特定性	<i>Differentiation (Syndrome)</i> 强调辨证施治
<i>Laboratory indications</i> 依赖实验室指标(直观)	<i>Four diagnostic approach</i> 四诊合参(抽象)
<i>Standard criteria</i> 诊断的统一性和标准化	<i>Individualization</i> 强调个体化的辨证
<i>Standard treatment</i> 治疗的统一性和标准化	<i>Individualized treatment</i> 个体化治疗及综合治疗方法

几种对照和区别

- Research on WM vs. Research on TCM

西医研究方法 与 中医药研究方法
强调机理 与 强调临床疗效

- Research on Traditional Chinese Medicine vs. Research on Chinese Herbs (Drugs)

中医研究与中药研究
强调中医辩证 与 强调有效成份

- Modernization of Traditional Chinese Medicine vs. Westernization of Chinese Herbs (Drugs)

中医现代化 与 中医西医化
用现代科学手段研究传统中医与改变传统中医以迎合西医

西药研究方法与中成药研究方法的对比

Comparison on Western Drug Development and Chinese Herbal Research

■ 西药研发

Western Drug Development

化学结构

Chemical structure

药物合成

Drug synthesis

体外实验

***In vitro* study**

在体实验 ***In vivo* study**

**I 期临床试验 Phase I
human clinical study**

**II 期临床试验 Phase II
clinical trial**

**III 期临床试验 Phase III
clinical trial**

■ 中成药研究

Chinese Herbal Research

已在临床应用多年

**Herbs in clinical use for many
years**

中药质量控制 **Herbal quality
control**

中药质量保证 **Herbal quality
assurance**

生物活性鉴定（体外实验）

Pre-clinical bioassay (*in vitro*)

动物毒性实验 **Animal toxicity
study**

**I/II 期临床试验 Phase I/II human
clinical study**

**III 期临床试验 Phase III human
clinical trial**

美国食品和药物管理局对植物药研发的指引 2004



U.S. Food and Drug Administration

Protecting and Promoting *Your* Health

MANUAL OF POLICIES AND PROCEDURES

CENTER FOR DRUG EVALUATION AND RESEARCH

MAPP 6007.1

POLICY AND PROCEDURES

OFFICE OF NEW DRUGS

Review of Botanical Drug Products

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如何用现代医学的科学方法评价古人的医疗方法？

**How can we evaluate the treatment skills developed by Zhang
Zhong-Jing using modern medical scientific methodology?**

策略和方法

Strategies and Methodology

- 循序渐进, 严谨踏实 进行有系统的研究

Phase-by-phase approach

- 用严密的科研方法但又不失中医的精华

Rigorous scientific research methodology that preserves the essence of TCM practice

- 最大限度地发挥中医的有效性但又不放弃

严格的科学研究方法

Maximizing TCM effectiveness within the scope of rigorous Western scientific research

- 鼓励转化医学, 基础研究须有临床意义

Encourage translational research with clinical implications

用严谨的科研方法同时保留中医的精华

**Rigorous Scientific Research Methodology
that Preserves the Essence of TCM Practice**

- **建立跨学科综合性研究团队**

Recruit a multidisciplinary research team

- **提出合适的研究问题**

Raise appropriate research questions

- **选择适合于中医治疗的病症**

Choose appropriate disease/symptoms

- **设计适当有效的中医治疗方案**

Select adequate TCM treatments

中医药在香港有着特定优势和良好的发展前景

CHM Will Have a Bright Future in Hong Kong Because of Its Unique Strengths

- 香港处于中西交汇的优势地位
- Hong Kong is unique because it is a crossing point between East and West.
- 有一流的中西医人才可组建强大的综合研究团队
- Top experts who can form a strong research team
- 有病人的需求，民间的推动，市场的导向
- Patient demand, community support, well-regulated market
- 有香港各大学中医院校的对中医药科研的热情
- Enthusiasm for CHM research in schools of Chinese medicine
- 有与国际，国内进行广泛交流的便利和优势
- Wide international and domestic connections
- 有香港特别行政区政府的支持
- CHM has Hong Kong governmental support

对中医药研究和发展几点建议

Suggestions for R&D in Chinese Medicine

1. 明确中医药在提高人们健康防治疾病的作用地位
 - 扬长避短, 发挥中医优势 (如应用太极拳, 气功, 食疗等)
 - 严格控制中药产品质量 (减低毒副作用, 标明西药成分)
2. 提出明确的研究目的和试验假设
 - 中医药对何种疾病或症状有效, 或无效?
 - 中药与中药, 中药与西药的作用关系如何?
 - 如何达到对某疾病/症状的最佳剂量的搭配?

3. 面对并解决目前中医药临床研究存在的方法学问题

- 研究应以解决科研问题为主，以病人利益为前提，而不应以经济利益为主
- 加强国际交流, 培养专业人才, 建立跨学科综合性研究团队
- 确立研究方向, 进行有系统的研究
- 基础研究需与临床试验, 临床应用挂钩
- 采用一切必要的和可行的循证医学研究方法
- 加强临床试验研究经费的投资比例
- 避免用行政手段来干预科学试验 (如不合理的时间限制)

谢谢聆听！

Thanks for Your Attention!