

# How can we optimise research integrating TCM with conventional healthcare practice?

Kelvin Chan <sup>a, b</sup> Nicola Robinson <sup>c</sup>

<sup>a</sup> University of Western Sydney, CompleMED, & <sup>b</sup> The University of Sydney, Faculty of Pharmacy, Australia  
<sup>c</sup> Faculty of Health and Social Care, London South Bank University, London SE1 0AA, UK

## Purpose

**Introduction:** Traditional Chinese medicine (TCM) is one of the most often used complementary medicines in Australia and worldwide by patients who have prior visits to western medicine (WM) care. Both paradigms have evolved under differently diagnosis and treatment principles to provide healthcare [1]. WM is facing the challenge of increasing costs in research of drug discovery and decreasing new effective drugs to alleviate chronic illnesses.

The aim of this presentation is to provide an overview on the recent assessment of good practice in TCM research published in literature, from which we can propose new directions to integrate these into conventional healthcare.

## Method

Literature review of key publications in TCM research, based on the EU-FP7-funded project "Good Practice in TCM Research (FP7 GPTCM) in the Post-genomic Era" [2], is utilised to illustrate how advances in technology in quality control of Chinese materia medica, biomedical studies using systems biology and adaptation of integrative research methods in clinical practice can provide integrative research methods with translational approaches in R&D of TCM, as indicated by review papers below:

- Good practice for reviewing and publishing studies on herbal medicine [3].
- Omics research in acupuncture to understand meridians and acupoints [4].
- Exploring practice and research of acupuncture in China and the EU [5].
- Future global regulation of Chinese herbal products [6].
- Omics and its potential impact on R&D and regulation of complex herbal products [7].
- Pharmacovigilance of herbal medicine, including TCM [8, 9].
- Assessing toxicity of herbal medicines [10].
- Integrating syndrome differentiation with orthodox medical diagnosis [11].
- R&D of high quality Chinese medicine products [12]

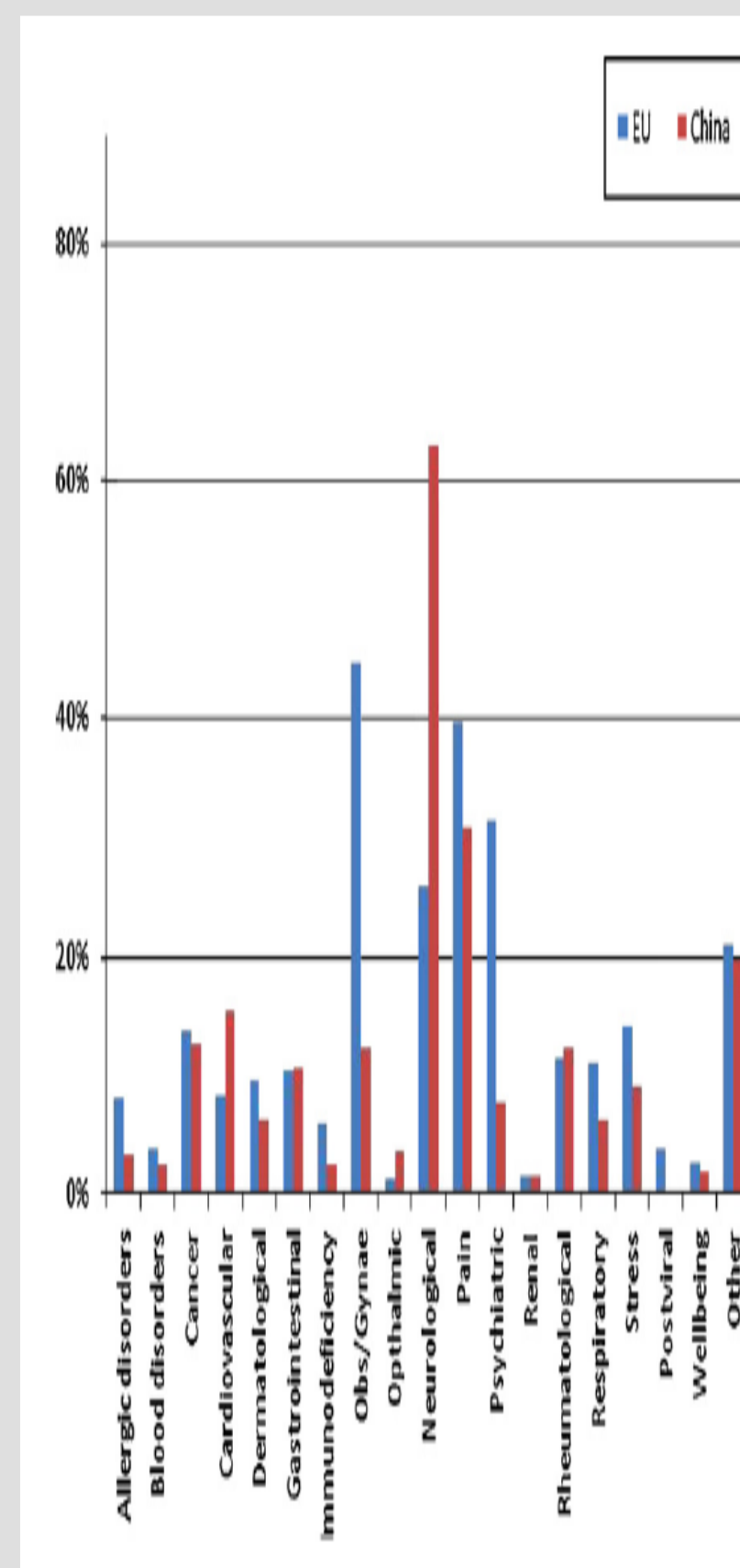
## Results

### Good Practice for TCM Research



### Acupuncture study

Overview of treated conditions in China and the EU

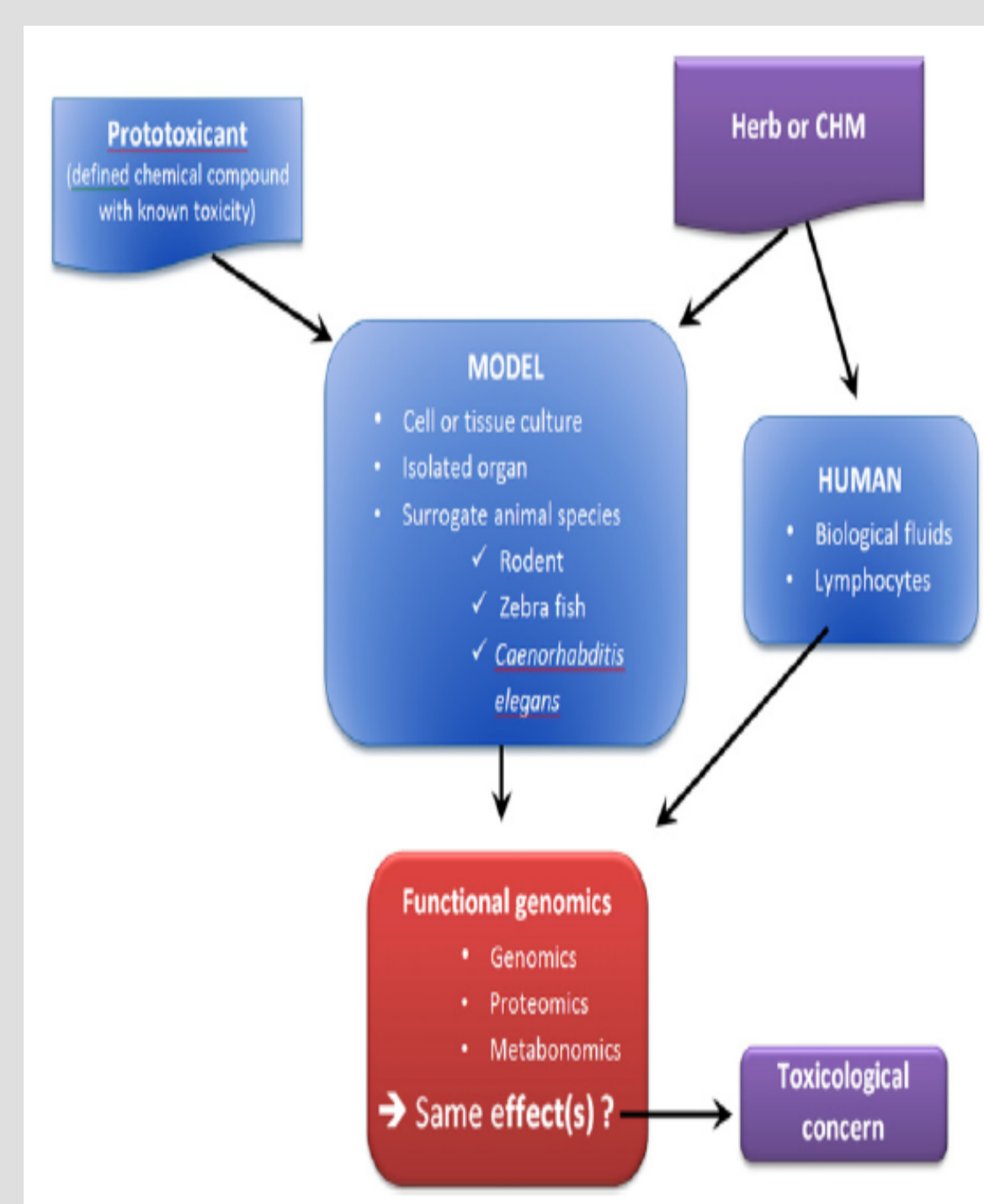


### Regulation of Chinese herbal products

Country/Region	Agency	Approach	Key Legislation	Key Agency
EU	National agencies in each country	Traditional herbal medicinal products (THMP) registration	Directive 2004/24/EC	The Commission on Chinese Medicine and Pharmacy, Department of Health
China	State Food and Drug Administration (SFDA)	Traditional Chinese Medicines (TCM) registration	TCM Regulation	The Ministry of Health, Library and Welfare
Japan	Pharmaceuticals and Food Sanitation Agency	TCM registration	TCM Regulation	The Ministry of Health, Labour and Welfare
South Korea	Ministry of Food and Drug Safety	TCM registration	TCM Regulation	The Ministry of Health and Welfare
Taiwan	Ministry of Health	TCM registration	TCM Regulation	The Commission on Chinese Medicine and Pharmacy, Department of Health

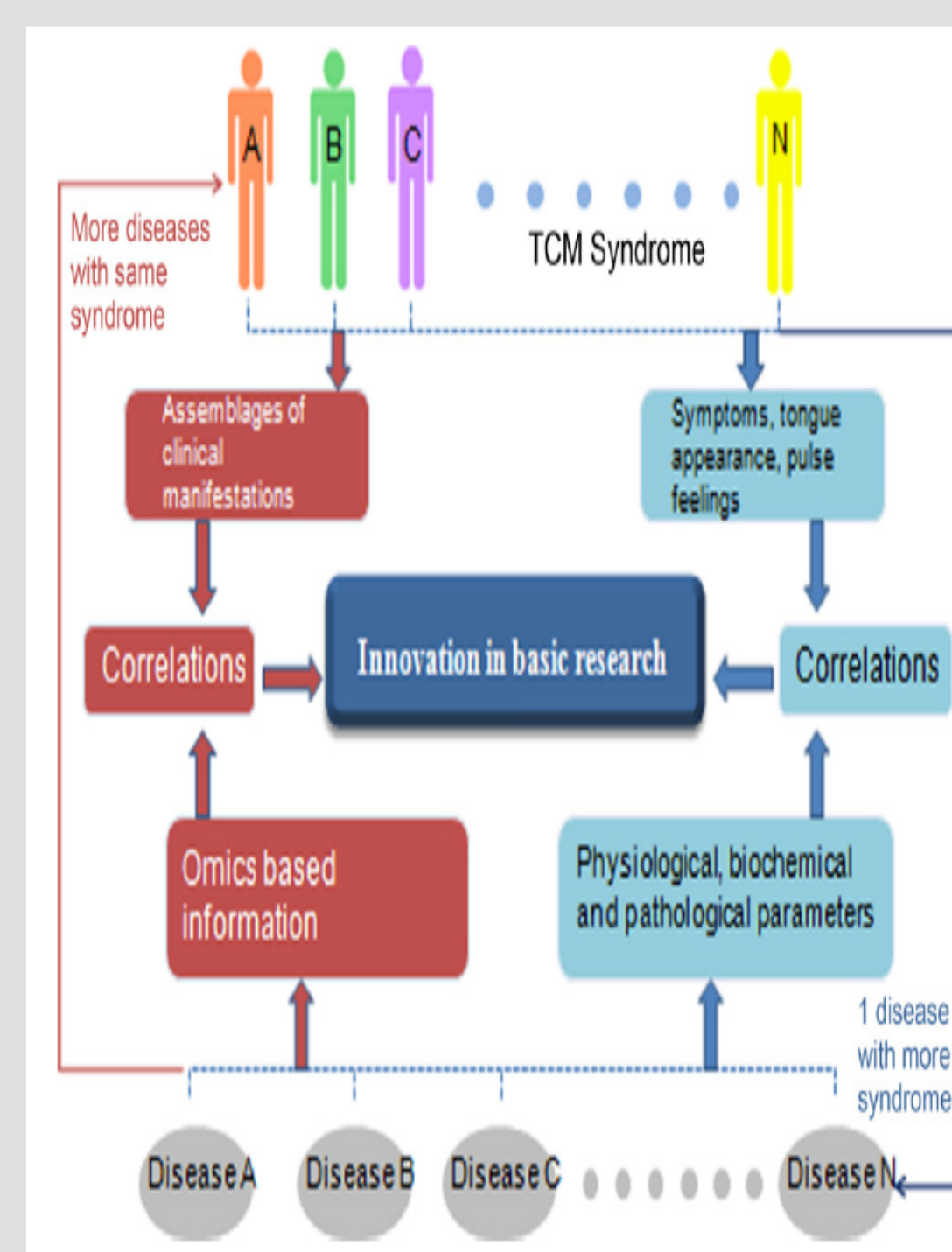
### Apply testing strategy from "omics" methods in screening herbal materials' toxicity

An in vitro or in vivo model is exposed to a chemically defined toxic with known properties ("prototoxicant"); the response of the model is evaluated by an "omics" method and possible biomarkers of exposure are examined. When the same model is exposed to an unknown compounds mixture or to an herbal extract, a similar pattern of response indicates probable toxicological concern. For traditional medicinal herbs or drugs that are classically used in humans, experimenters additionally may have access to patients body fluids (urine, blood) to investigate for eventual toxicity biomarkers, an important avenue for research but also for patient's monitoring.



### Apply TCM syndrome differentiations in modern innovative R&D in TCM.

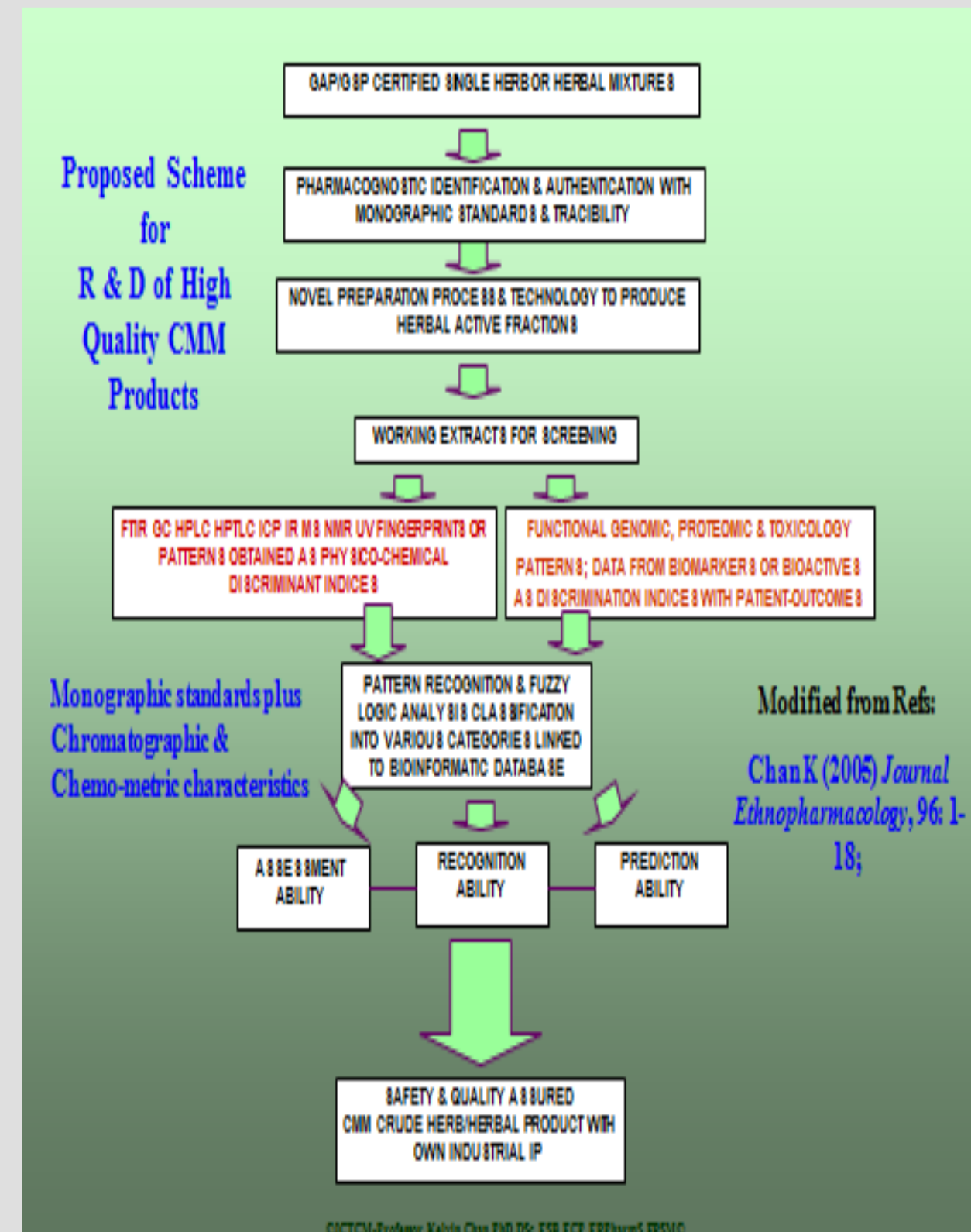
The correlation can be applied either between TCM symptoms (including tongue appearance and pulse feeling) and biological parameters in biomedicine, or between TCM syndrome (assemblages of clinical manifestation) and omics parameters/ biomarkers in biomedicine.



### Apply functional genomics and proteomics to screening Chinese materia medica



### Reversed pharmacological screening for R&D of niche Chinese medicines



## Discussion

- There are differences in practice and training between acupuncturists in China and in the EU .
- Disease-oriented studies using the approach of multi-indexed high-throughput technologies and systems biology analyses will be a preferred strategy for future R&D of Chinese medicine.
- International collaboration and harmonization is essential for regulation of good quality Chinese medicine products.
- Development, dissemination, implementation and refining of good practice guidelines in reviewing and publishing research findings on traditional medicine are matters of vital importance.
- Combining the systems biological investigations of mechanisms of actions of Chinese medicines, ensuing identification of potential biomarkers to be associated with both Western disease concepts and TCM pattern classifications and QOL instruments to monitor patient-reported outcomes, which are in the heart of personalized medicine, would offer common ground for integration [1].
- Effective pharmacovigilance is essential for the development of appropriate guidelines for safe, effective use of herbal medicines including those derived from Chinese materia medica.
- Structural alerts and *in silico*, *in vitro* and *in vivo* methods could be applied to predict the genotoxicity, teratogenicity and nephrotoxicity of Chinese medicinal products.
- Research in TCM syndrome differentiation will provide the basis of the molecular network of TCM syndrome differentiation for some disease types, in defining the potential mechanism of Chinese medicines.

## Conclusion

- Continuing effort in scientific and practice research and development is key to provide new knowledge for training new generation of human resource in integrative medicine that involves TCM practice.
- Research linking the relatively new systems biology and experience-based TCM principles will be useful to interpret the holistic approach of TCM towards integrative medicine.

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