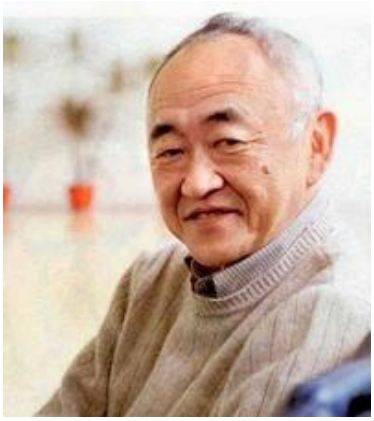
MERRY CHRISTMAS & HAPPY NEW YEAR!

Warmest congratulations to Prof. Yung-Chi CHENG for being awarded the prestigious *Cheung On Tak International Award for Outstanding Contribution to Chinese Medicine!*



Professor Tommy Yung-Chi Cheng

As reported in June 2011, Professor Cheng was nominated by the GP-TCM Coordination Office (www.gp-tcm.org/wp-content/uploads/2011/06/GP-TCM_May-June_2011.pdf). GP-TCM Advisor Prof. Yi-Tsau HUANG (National Research Institute of Chinese Medicine, Taiwan), GP-TCM Advisor Prof. Gang PEI (Tongji University, Shanghai) and Prof. Yao TONG (The University of Hong Kong) also independently nominated Prof. Cheng for the award. The official selection statement can be viewed on http://scm.hkbu.edu.hk/en/cm-award/intro/stat_tommy.html

Here, let's revisit the GP-TCM nomination in honour of Prof. Cheng:

"Professor Cheng is a world-leading educationalist, scientist and innovator in both Western and Chinese medicines. He has trained generations of scientists worldwide, published hundreds of original research papers in high impact journals including *Nature* and *Science*. In addition to the Cheng-Prusoff equation (1973), which is still used by pharmacologists worldwide today, he has also developed four Western drugs that are widely prescribed helping patients fight against diseases. Among his numerous achievements, we wish to nominate Professor Cheng for this prestigious award because we believe he is unquestionably a preeminent leader in (i) disseminating the science and culture of traditional Chinese medicine (TCM), (ii) developing new concepts, technologies and platforms for truly translational research of TCM, and (iii) organising international, intersectoral and interdisciplinary dialogues and collaborations. Professor Cheng's main achievements in the field of TCM research are:

- Bridging TCM research in mainland China, Taiwan, Hong Kong, Macau and many other Asian regions with the rest of the world, as illustrated by his honorary appointments and tireless activities in these areas.
- Bringing TCM into the mainstream of industrial development through founding PhytoCeutica Inc., developing an innovative "Photomics Quality Control" technology approved by the US Food & Drugs Administration (FDA) and applying it to the modernisation of a TCM formula Huang Qin Tang into a new type of botanical drug, PHY906, which has recently passed phase II clinical trial in the USA. In this process, Prof. Cheng pioneered the positive interactions with key stakeholders such as National Institutes of Health (NIH), FDA, universities, industries and public media.
- Bringing TCM research into the mainstream of international academic community through pioneering investigations of PHY906, leading to ground-breaking publications in leading journals such as *Science Translational Medicine*, in which he provided unequivocal evidence that all four herbs in Huang Qin Tang are required to produce optimal therapeutic effects, validating the principle of Jun-Chen-Zuo-Shi (君臣佐使).
- Founding the Consortium for Globalisation of Chinese Medicine (CGCM) in 2003; since then, under Prof. Cheng's chairmanship, CGCM has constantly grown into a truly international organisation with more than 130 institutional members and industrial affiliates. As one of the largest international organisations dedicated to promoting TCM culture, education and research, CGCM is united under the banner of "globalised Chinese medicine", an innovative concept first developed by Prof. Cheng and his CGCM co-founders. Striving to further develop TCM into a "globalised Chinese medicine" so that it can better serve the different needs of peoples around the world, CGCM organises regular meetings and collaborations among its members, including the Good Practice in Traditional Chinese Medicine Research in the Post-genomic Era (GP-TCM) consortium, and is an unraveled non-governmental force in the cause of internationalisation and modernisation of TCM.
- Supporting TCM research in Europe, by promoting

European membership development and firmly supporting their initiatives in TCM research, as illustrated by his chairmanship of our Advisory Board and his continuous support to our meetings, research and grant application efforts. Inspired by CGCM and Professor Cheng, GP-TCM, the first ever EU-funded 7th Framework Programme (FP7) coordination consortium, strives to inform the best practice and harmonise research on the safety and efficacy of TCM through interdisciplinary exchange of experience and expertise among clinicians and scientists. With its increasingly large pool of expertise across 23 countries including 15 EU member states, the consortium provides forums and collaboration platforms on quality control, extraction technology, component analysis, toxicology, pharmacology and regulatory issues of Chinese herbal medicine, as well as on acupuncture studies, with particular emphasis on the application of a functional genomics approach."

The other award winner is Prof. Ke-Ji CHEN, China Academy of Chinese Medical Sciences. **We warmly congratulate both Professor Yung-Chi CHENG and Professor Ke-ji CHEN for their great achievements and the award!**

GP-TCM events and activities:

1. The 1st GP-TMR Elections for President, President-Elect and Board of Directors (BoD): The GP-TMR/GP-TCM Association election is well in progress. The GP-TCM Coordination Office received 1 application for the President position (Professor Rudolf BAUER, Graz, Austria), 1 application for the President-elect position (Professor De-an GUO, Shanghai, China) and 27 applications for BoD membership: http://www.gp-tcm.org/2011/12/1st-gp-tmr-election-candidates/. All GP-TCM members should have received invitation for casting your votes.

Based on the election rules (http://www.gp-tcm.org/wp-content/uploads/2011/12/Election-rules-Final2.pdf), Prof. Bauer and Prof. Guo are elected President and President-elect by acclamation. The GP-TCM Coordination Office warmly congratulate them for being elected and thank them for their courage and commitment to leading the development of a new association towards prosperity. Although they are elected by acclamation, their appointments will not be officially announced until the end of the election in mid-January, along with the BoD members. The online voting facility still allows you to cast your votes, not only for BoD members but also for the President and President-elect. Please show your support and care about GP-TMR using your voting power. Thanks!

Should you have any questions about the election please e-mail Dr. Halil UZUNER (halil.uzuner@kcl.ac.uk) and Dr Xuebin DONG (xuebin.dong@kcl.ac.uk).

2. The GP-TCM Final Conference will be held in Kerkrade, the Netherlands, on 12th – 13th April 2012.

Conference Centre Rolduc, Kerkrade, the Netherlands

The final conference of the consortium, which aims to disseminate the work and findings of the project, will take place in Kerkrade, the Netherlands on 12th – 13th April 2012. Kerkrade is located close to Belgium and Germany and can be easily reached by public transport or by car. From Schiphol airport (Amsterdam), it is possible to reach Kerkrade by train. Near Kerkrade are Maastricht–Aachen, Liège, and Düsseldorf airports. The venue for the final conference is "Conference Centre Rolduc". Please visit the conference centre website (http://www.rolduc.com/index.php?lang=en) as well as the WP9 homepage (http://www.gp-tcm.org/2011/04/final-conference/) for further details.

If you travel from one of the above airports to Kerkrade by train, the website of the Nederlandse Spoorwegen or OV9292 can be useful. If you prefer to drive, the website of the ANWB can be of help (in Dutch).

The Final Conference agenda will be finalised in late 2011 - early 2012 and announced at the GP-TCM website. Web link will be provided in the consortium newsletter for your convenience.

3. The GP-TCM congress will be held in 15th – 18th April 2012 in Leiden, the Netherlands: Following the Final Conference, which is by invitation only, a public international event "GP-TCM Congress" will be held in Leiden to disseminate the work and findings of GP-TCM to a wider audience. The Congress will be held from 15th – 18th April 2012 at "Gorlaeus Laboratories" in Leiden University, Leiden (http://visitors.leiden.edu/buildings/gorlaeus.html). Please visit the Congress website for further details (http://www.gp-tcm-congress.nl/). The Congress agenda will be finalised in early 2012 and announced at the GP-TCM website. Web link will be provided in the consortium newsletter for your convenience.

Gorlaeus Laboratories, Leiden, the Netherlands

Appointment of new consortium members:

1. Appointment of Dr. Xuebin DONG (King's College London, UK) as the Deputy Coordinator of WP5 (*In Vivo* Studies of CHM): Xuebin is an existing beneficiary member of the GP-TCM consortium who has been actively involved in WP5 literature reviews and in organising the 1st GP-TMR election. Xuebin obtained his MD and PhD in China and came to the UK in 1999. He is a clinician-turned scientist and an expert of animal studies. Xuebin is an experienced organiser and enabler. He served as Co-Chairman of the Chinese Students and Scholars of Central London (2003-2004) and has been the Treasurer of the Chinese Life Scientists Society in the UK since 2006. **Warmest congratulations, Xuebin!**

2. Appointment of Dr. Ivano EBERINI (University of Milan, Italy) to GP-TCM as a non-beneficiary member devoted to WP4 (Functional Genomics of Chinese Herbal Medicine Research In Vitro). In the course of time, Ivano's commitment has remained with the investigation of structure-function relationship in proteins, such as carriers or receptors, able to bind small-size ligands. His research interest has progressively focused from more general to more detailed issues while the procedures he has used for his analysis have shifted from in-vivo to in-vitro and to in-silico work. His interest in computational pharmacology arose during the preparation of his PhD thesis and has grown since. In ten years, Ivano co-authored 69 scientific papers, with a cumulative IF of 257 and approx. 1300 citations. His research activity is typically interdisciplinary encompassing biochemistry, molecular pharmacology and biophysics. The drug discovery pipeline developed in Ivano's research group revealed itself as a good approach for identifying new putative candidates for targeted therapy. The first results obtained in this field were published and an Italian and European patent was deposited in 2010. **Warmest welcome and congratulations, Ivano!**

3. Appointment of Dr. Thomas EHRMAN (King's College London, UK) to GP-TCM as a non-beneficiary member devoted to WP4 (Functional Genomics of Chinese Herbal Medicine Research In Vitro). Tom Ehrman originally obtained a degree in botany from Cambridge University (UK), before working for several years as a plant collector for two international organizations, in the field of the plant genetic resources. He has studied and practised both western and Chinese herbal medicine, and is a member of the UK register of Chinese Herbal Medicine. In 2002, he was awarded an MSc in computational chemistry, before completing a PhD at King's College London (UK) in pharmacy, specializing in phytochemical informatics, with a focus on traditional Chinese medicine. He has published a number of recent articles on virtual screening of Chinese herbs, among them two attempts to use cheminformatics to find relationships between the chemical composition of Chinese herbs and their traditional uses, as described in the language of TCM. He was involved in a collaborative project between the Institute of Materia Medica (Shanghai) and King's College London, combining the development of a database of Chinese herbal constituents with virtual screening against a variety of well-known molecular targets, using both ligand and protein-based methods. He is currently developing an information resource on natural products, involving both text mining and cheminformatics, with an emphasis on integrated search and visualization. **Warmest welcome and congratulations, Tom!**

4. Appointment of Dr. Raymond Cheun-Chung CHANG (University of Hong Kong (HKU), Hong Kong SAR, China) to join GP-TCM as a non-beneficiary member dedicated to WP10 (Management). Raymond, currently an Assistant Professor at HKU, received his BSc in Biochemistry and MPhil in Neurochemistry and Neuroanatomy training in Hong Kong. He received a research scholarship by German Academic Exchange Service (DAAD) to pursue his doctoral training in neurophysiology and clinical neuroscience at the University of Munich, Munich, Germany. Afterwards, he continued his postdoctoral training in neuropharmacology and molecular neuroscience at NIEHS/NIH, USA. During that time, he received the Visiting Research Fellowship Award and the NIH Fellow Award for Research Excellence by the NIH. He has published over 80 peer-reviewed publications and book chapters in neurodegeneration, neuroimmunology and drug discovery. Raymond is now the Scientific Advisory Board member in International Alzheimer's/Parkinson's Diseases Symposium, editorial board member of journals such as Journal of Alzheimer's Disease and is also the Founder and Secretary of HKU Alzheimer's Disease Research Network. Raymond's research interest is to investigate

molecular mechanisms of neurodegeneration in Alzheimer's disease, Parkinson's disease, glaucoma and aging-related macular degeneration (AMD) so that pharmacological targets and therapeutic intervention from herbal medicine can be found. He has been investigating Wolfberry (*Lycium barbarum*) as an example of anti-aging Chinese medicine. **Warmest welcome and congratulations, Raymond!**
http://www0.hku.hk/anatomy/staff/RCCChang.html

5. Appointment of Prof. Yuan Shiun Chang (China Medical University, Taiwan) to GP-TCM as a non-beneficiary member devoted to WP7 (Commercial R&D).

Dr. Yuan Shiun Chang (張永勳) is Professor of Pharmacognosy at the School of Chinese Pharmaceutical Sciences and Chinese Medicine Resources, College of Pharmacy, China Medical University, Taichung, Taiwan. He received his Ph.D. degree in pharmacognosy from University of Illinois at Chicago, Illinois, U.S.A. in 1989 under the supervision of late Professor Norman R. Farnsworth. Besides teaching, Professor Chang had served as Head of Herbal Pharmacy of China Medical University Hospital for more than 10 years. He collaborates closely with TCM communities in Taiwan, and organized various workshops and symposia for TCM practitioners. He had served as member of Committee of Chinese Medicine and Pharmacy, Department of Health, Taiwan for many years. Professor Chang is engaged in the quality control studies of TCM herbs including chemical specification of TCM herbs, sulfur dioxide residue, pesticide residue and aflatoxin content, etc. Currently the key person in Taiwan for the revision of Taiwanese Herbal Pharmacopeia, Professor Chang has also been invited in 2011 to join Hong Kong Chinese Materia Medica Standard project as a PI from China Medical University. To date, he has published 130 scientific papers and 14 books in TCM fields, as well as contributing to the WP7 review "Future Development of Global Regulations of Chinese Herbal Products" for the GP-TCM Special Issue of *Journal of Ethnopharmacology*. **Warmest welcome and congratulations, Yuan Shiun!**

Editor's Choice:

Nature Outlook: Traditional Asian Medicine. *Nature* Vol. 480 No. 7378_supp ppS81-S121. **Free full access.**
http://www.nature.com/nature/outlook/asian_medicine/?WT.i_dcsvid=%25%25LIST_ID%25%25-%25%25RECIPIENT_ID%25%25&WT.ec_id=MARKETING#editorial

Using scientific techniques to investigate the claims of traditional medicine as practised in countries such as China and Japan can help sort effective treatments from unfounded superstitions — and perhaps give modern medicine a few insights into holistic approaches borne from thousands of years of herbal remedies.

Further reading:

1. The WHO International Classification of Traditional Medicine project: GP-TCM members involved in this project are Dr. Meng CUI (China), Dr. Vivian Chi-Woon WONG (Hong Kong), Dr. Deborah SHAW (UK), et al.

(1) Why and how WHO will develop a standardized international system for classifying Traditional Medicine?
https://docs.google.com/viewer?a=v&pid=sites&srcid=ZGVmYXVsdGRvbWFpbnx3aG9pY3RtfGd4Ojc5YzU5OTU1MTkyZWZmMjc
(2) Resources documents:
https://sites.google.com/site/whoictmdocs/
(3) Press release:
https://sites.google.com/site/whoictm/press
(4) Participants:
https://sites.google.com/site/whoictm/participants

2. A Different Culture by Bill Cooney, President and CEO; MedPoint Digital, Evanston, Ill. *Drug Discovery & Development* – 1 August, 2011

Editor's note: This is a thought-provoking article on problems encountered when delocalizing clinical trials. The author also touched on trials combining western and traditional medicines.

Over the last decade, research programs have expanded offshore into Eastern Europe, Latin America, and Asia-Pacific. This has been driven in large part by escalating costs and difficulties associated with patient recruitment in North America and Western Europe. Between 2005 and 2006, the number clinical trials conducted in the Asian-Pacific region increased by 50%.

This expansion into emerging regions hasn't stopped clinical trials from becoming increasingly complex and dependent on sophisticated technology systems. A study by the Tufts Center found that the median number of procedures per clinical trial increased by 49% between 2000-2003 and 2004-2007, while the total effort required to complete those procedures grew by 54%.[1] Trial complexity has been further compounded by the proliferation of digital study systems.

Among the advantages of conducting trials offshore are concentrated populations in urban centers and a relative abundance of investigators who have been educated in the West. This profile has led to the assumation that conducting clinical trials in such regions is similar to working in Western markets. Over time, however, the research community has realized that important differences exist and success can depend on taking these into account.

Culture trumps all There are profound differences across cultures in how people learn and communicate, and an understanding of these differences is essential for any endeavor in emerging regions. Indeed, the maxim "culture trumps strategy" has recently arisen, and it might be better said, "Culture trumps all." Study managers must consider the unique cultural landscape of every country in which they operate.

Among many important cultural factors, communicators must consider differences in providing feedback, asking questions, taking tests, group dynamics, individual roles, relationship building, and social hierarchies, to name just a few. Communication programs and training plans need to accommodate a wide range of such cultural dynamics.

Some generalities apply for effective communications within specific countries, but each culture presents communicators with multiple nuanced challenges. It may be unrealistic to expect study leaders to understand the cultural nuances of every country involved in an offshore clinical trial. Instead, study leaders must rely on feedback from members of the study support team, such as regional affiliates of the drug developer or contract research organization (CRO) personnel who are resident within respective countries.

Socio-economic diversity In addition to culture, socio-economic factors play an important role in communicating in offshore trials. In some less affluent countries, large parts of the population may not have access to adequate health services, and clinical trials may be the only way for some patients to gain access to modern healthcare. In such settings, the need to ensure that patients provide their informed consent is one of many clear communications challenges.

Literacy rates tend to vary more widely among emerging countries, and there is even a wide range of literacy rates among regions within countries such as India and China. This requires a partnership among governments, drug developers, and medical providers to protect illiterate patients from potential abuse in clinical trials. In such cases, informed consent may need to be documented by the patient, study site staff, and independent witnesses.

Language barriers English has become the de facto standard for communications in offshore clinical trials, but the reality is that English fluency varies among global study sites and there are important language factors to consider. Even for study site investigators and coordinators who speak English as a second language, proficiency can vary widely and affect training. In some offshore countries such as India, Hong Kong, and the Philippines, English is widely spoken among sectors of the population and is even one of the official languages. High rates of English proficiency are helpful, but can cause developers to underestimate the important cultural differences that exist in such countries. And while English proficiency in these countries is excellent among medical professionals, less educated patient populations may not have as reliable English skills.

At a minimum, many countries require that regulatory documents and patient information be translated into all official languages. Patient materials pose special

translation challenges in countries with multiple native languages, and this can become a burdensome aspect of communicating in offshore trials.

Modern and traditional medicine Training and communications plans may be affected by important differences in medical practices within various regions. Direct experience with clinical research and baseline knowledge of good clinical practice may vary widely from country to country, as may the character of general medical training.

The day-to-day roles and interactions between physicians and non-physician healthcare professionals may be very different among countries. To respect the hierarchical sensitivities of some cultures, it may be necessary to train and communicate with physicians separately from non-physicians such as study coordinators. It's also imperative to understand how duties in the conduct of studies are divided among investigators and their staff.

The attitudes and behaviors of patients with caregivers can also differ markedly among different countries and regions. Trial leaders face the difficult challenge of balancing cultural sensitivity with the absolute need to conform to Western standards such as ICH/GCP.

In many emerging regions, medical practice often combines Western medicine with traditional medical approaches, and study teams need to understand local medical practices, anticipate possible affects on the protocol, and effectively communicate on how to appropriately execute clinical trials in such practice settings.

Many emerging countries are rapidly improving their regulatory regimes, adoption of ICH/GCP guidelines, and standards of transparency. However, it's important to closely track the state of development in each country and communicate the most current information to all parties, including field monitors and study sites.

Evolving infrastructure Technology and logistic infrastructure can also affect communication plans. As the exchange of information moves into digital media, it becomes important to consider regional issues such as the availability of broadband connectivity, computer hardware, and software resources, and even basic computer skills among study site personnel.

Logistically, travel and face-to-face communications can be constrained by costs, visa requirements, security concerns, and even freedom of movement in some regions. Meeting and training plans need to incorporate these special logistical considerations.

Local partners Perhaps the most important element for effective communications is the involvement of nationals from the countries of offshore study sites. Some drug developers have extensive affiliate offices across the globe, with local staff members who can assist with culturally adjusted communications. If that's not the case, study leaders may gain support from the growing number of CROs that are available in many emerging countries. Local staff or CROs can serve as an important bridge between the goals and processes of a study, and the cultural context in which the study will operate.

Virtual media Virtual media has the potential to dramatically lower costs, improve availability, and expedite delivery of effective training and communications. This is especially true for emerging regions, where issues of cost, quality, and logistics are accentuated.

Use of both live virtual media (Web conferences) and on-demand virtual media (Web sites) is booming in clinical research. For live Web conferences, it is imperative to use a skillful mix of multimedia and interactive elements to hold audience attention and achieve communications goals. For Web sites and self-learning modules, it's important to add production elements that contribute to a superior user experience, such as animation effects and navigation tools that let users control the pace and sequence of material. Audiences that speak English as a second language can especially benefit from self-learning modules that include scrolling text of speaker comments, because such audiences often have better reading skills than listening skills.

Culturally attuned communications may be among the most important factors for success in offshore clinical trials. The clinical research community has made important strides in better understanding new cultural settings, and study leaders must incorporate cultural understanding across the full range of their training and communications activities.

Bill Cooney founded MedPoint in 1990 and has presided over the growth and transformation of MedPoint into a provider of digital medical communications and information services.

Reference

1. March/April 2010 CSDD Impact Report. Tufts Center for the Study of Drug Development. Available from http://csdd.tufts.edu/files/uploads/mayjuneimpactrpt10summary.pdf Accessed on July 15th, 2011.

Acknowledgment: Many thanks for the contributions by Prof. **Yuan Shiun CHANG** (Taiwan), Prof. **Pierre DUEZ** (Belgium), Dr. **Ivano EBERINI** (Italy), Dr. **Thomas EHRMAN** (UK), Dr. **Halil UZUNER** (UK), Dr. **Marianne VERBERNE** (the Netherlands), Prof. **Yi-Tsau HUANG** (Taiwan) and Dr. **Qihe XU** (UK).