Advanced Clinical Trials China (ACT China II)

国际临床研究高级研修班

30 November - 2 December 2012

2012年11月30日至12月2日

The Vanburgh Hotel, Guangzhou PRC

中国广州云来斯堡酒店

FRIDAY, 30 NOVEMBER

Time	Subject	Speaker/Chair
08:45	Assemble in hotel lobby–Hospital Visiting Tour; return at 11:00	Guangdong General Hospital
11:30–12:30	Lunch （Wan Hin)	
12:30–14:00	Final Slide Review (Hong Yun Hall)	
Co-chairs: Prof. Yi-Long Wu and Prof. Shukui Qin (Hong Yun Hall)		
15:00–15:15	ACT China II Welcome and introduction	Yi-Long Wu, Shukui Qin, Martin J. Murphy
15:15–15:45	Ethical considerations in clinical trials	Patrick G. Johnston
15:45–16:00	Q&A	
	Phase I clinical trials	
16:00–16:30	Phase I clinical trials: objectives, design, and endpoints	Lillian L. Siu
16:30–16:45	Q&A	
16:45-17:00	Afternoon tea	
17:00–17:30	The Contribution of Phase I to Phase II and III	Jin Li
17:30–17:45	Q&A	
17:45–18:15	Pharmacokinetics, pharmacodynamics, and identifying adverse events in Phase I clinical trials	Lillian L. Siu
18:15–18:30	Q&A	
18:30-19:00	Panel discussion	CSCO and Visiting Faculty
19:30–21:00	Dinner (Wan Hin)	

SATURDAY, 1 DECEMBER

Time	Subject	Speaker/Chair
Co-chairs: Prof. Yi-Long Wu and Prof. Patrick Johnston (Hong Yun Hall)		
08:00–08:15	Welcome and housekeeping announcements	Yi-Long Wu, Patrick G. Johnston, Martin J. Murphy
08:15–08:45	The principal investigator's responsibilities in conducting clinical trials	Richard L. Schilsky
08:45–09:00	Q&A	
	Phase II clinical trials	
09:00–09:30	Objectives, design considerations and endpoint selection for Phase II clinical trials	Richard L. Schilsky

SATURDAY, 1 DECEMBER (continued)

09:30-09:45	Q&A	
09:45-10:00	Morning tea	
10:00–10:30	Statistical considerations for Phase II trials and adaptive design	J. Jack Lee
10:30–10:45	Q&A	
10:45-11:15	The importance of cooperative network for clinical trials	Yi-Long Wu
11:15–11:30	Q&A	
11:30-12:00	Panel discussion	CSCO and Visiting Faculty
12:00–14:00	Lunch (Wan Hin)	
14:00–15:45	Simultaneous workshops:	Workshop co-chairs:
	1. Phase I clinical trial development (Ball Room C)	Lillian L. Siu, Jin Li
	2. Phase II clinical trial development in Lung cancer (Ball Room B)	Shun Lu, Tony Mok
	3. Phase II clinical trial development in Breast cancer (Rui Yun Hall)	Binghe Xu, Ning Liao
	4. Phase II clinical trial development in Gastrointestinal cancers (Xiang Yun Hall)	Shukui Qin, Richard L. Schilsky, Patrick G. Johnston
15:45–16:00	Afternoon tea	
Co-chairs: Shukui Qin and Richard L. Schilsky (Hong Yun Hall)		
16:00–16:30	Regulatory considerations	Patrick G. Johnston
16:30–16:45	Q&A	
	Phase III clinical trials	
16:45–17:15	Phase III clinical trials: objectives, hypothesis, and design considerations	Tony Mok
17:15–17:30	Q&A	
17:30–18:00	Statistical issues in Phase III randomized clinical trials: interim analysis and data monitoring	J. Jack Lee
18:00–18:15	Q&A	
18:15-18:45	Panel discussion	CSCO and Visiting Faculty
19:30–22:30	CSCO gala banquet and social event (Restaurant Bingsheng)	

SUNDAY, 2 DECEMBER

Time	Subject	Speaker/Chair
Co-chairs: Shun Lu and Lillian L. Siu (Hong Yun Hall)		
08:00–08:10	Announcements	Shun Lu, Lillian L. Siu
08:10–08:40	Lessons learned from GI clinical trials	Patrick G. Johnston
08:40–08:55	Q&A	
08:55–9:55	Reports from workshops (15 minutes each)	Nominated Representatives
09:55–10:15	Building Bridges to Conquer Cancer	Doug Pyle, ASCO
10:15–10:30	Morning tea	
10:30–11:00	Lessons learned from gefitinib and crizotinib clinical trials in NSCLC	Shun Lu
11:00–11:15	Q&A	
11:15–12:00	Summary panel discussion	Richard L. Schilsky, Shukui Qin
12:00–12:15	Closing remarks	Yi-Long Wu, Shukui Qin, Martin J. Murphy
12:15 – 13:15	Lunch (Wan Hin)	

Dear Colleagues,

On behalf of the Steering Committee, it is with great pleasure that we welcome you to the **Advanced Clinical Trials China II** (ACT China II) **Workshop**, held in partnership with the *Chinese Society of Clinical Oncology* (CSCO), the *Society of Translational Oncology* (STO), USA and *American Society of Clinical Oncology* (ASCO). This workshop promises to be an exciting and enlightening one, with presentations and discussions which will provide insights into the essential elements of clinical trial design, execution and interpretation.

Clinical trials play a vital role in improving the outcomes of cancer patients as well as in the drug development process. They account for a significant proportion of total research and development expenditure. Pharmaceutical companies today face an ever growing demand from regulators and patients to expand their clinical trial programs. While there are clear benefits for the conduct of clinical trials in China, it is also acknowledged that there are several key issues concerning clinical trials in China which need to be addressed. It is important that steps be taken to align Chinese clinical trial standards with those used internationally as this will enable more Chinese cancer centers and their investigators to participate in more international studies. This is where **ACT China** plays a crucial role.

In its mission statement, CSCO states that it is committed to developing continuing education and training programs for oncology professionals in China. Similarly, STO and ASCO maintain a strong commitment to clinical trial excellence. With **ACT China**, CSCO, STO and ASCO are united in a common goal – the global fight against cancer.

Over the course of this 3-day workshop, a global faculty of experts will address the current issues and challenges in carrying out Phase I, II and III clinical trials through a series of lectures and discussions and workshops. We believe that the curriculum we have designed – covering ethics, preclinical studies, clinical trial design and conduct, statistics and regulatory considerations – will help transform oncology research in China for the benefit of cancer patients in China and around the world.

As part of our commitment to clinical trial excellence, it is our hope to deliver this program to a wider audience in the future and hence your active participation and feedback is most appreciated. We appreciate the continued Charter Sponsorship of ***Sanofi Oncology.*** We are also thankful to ***Shanghai Roche Pharmaceuticals Ltd*** and to ***Boehringer Ingelheim*** and ***Quintiles*** for their sponsorship of **ACT China II**.

Last but not least, we hope that you will find this workshop rewarding and informative.

Professor Shukui Qin
Co-Chair, **ACT China**
President, Chinese Society of Clinical Oncology

Professor Yi-Long Wu
Host & Co-Chair, **ACT China**
President-elect, Chinese Society of Clinical Oncology

Dr. Martin J. Murphy
Convener, STO
Chair, Conquer Cancer Foundation of ASCO

Prof. Shukui Qin, graduated from Nanjing Railway Medical College in 1982, is a senior medical oncologist, especially focusing on the clinical practice and research in Gastro-intestinal cancers as well as Liver cancer. He acts as the Senior Vice-President of Nanjing Bayi Hospital and Director of PLA Cancer Center.

Up to now, Prof. Qin has published both more than 440 medical papers in peer reviewed journal and 49 academic works, and participated in more than 140 international and domestic multi-centers clinical trials. Prof. Qin's outstanding contributions to both academic and research fields were highly rewarded including more than 20 Chinese National and Provincial scientific awards and Chinese Government Special Talent Allowance.

Prof.Qin holds a series of important positions in international and domestic academic organizations, including President of Federation of Asia Clinical Oncology (FACO), Council Member of Society of Immunotherapy of Cancer (SITC), Senior Council Member of Asia Clinical Oncology Society (ACOS), President of Chinese Society of Clinical Oncology (CSCO), Senior Council Member of Chinese Anti-Cancer Association (CACA), Chairs of Liver Cancer group and Cancer Pain Control group of National Ministry of Health, etc. And he acts as the Editor-in- Chief of "Journal of Chinese Clinical Oncology" and "The Oncologist (Chinese edition)" , the Associate Editor-in-Chief of "Chinese Clinical Oncology Year-Books", "Journal of Cancer Research and Clinical" and "The Chinese-German Journal of Clinical Oncology" etc.

Prof. Yi-long Wu is a vice-president of the Guangdong General Hospital & Guangdong Academy of Medical Sciences and a director of Guangdong Lung Cancer Institute. He is the president elect of Chinese Society of Clinical Oncology （CSCO）, the past director of Chinese Society of Lung Cancer (CSLC), the President of the Chinese Thoracic Oncology Group(C-TONG), the President of International Chinese Society of Thoracic Surgery (ICSTS), a Fellow of the American College of Surgeons, a Member of staging committee of the International Association Study of Lung Cancer (IASLC) and a Member of the International Affairs Committee of ASCO.

His research interest is the multi-disciplinary synthetic therapy on lung cancer from basic to bedside and Evidence-Based Medicine on Oncology. He presented many clinical evidences such as Chinese lung cancer staging, neoadjuvant and adjuvant chemotherapy, target treatment data in international lung cancer society. He has been as an invited speaker in numerous international lung cancer congresses and has chaired many national meetings. He has published 19 books and more than 300 academic papers in peer reviewer international journals or national journals among 80 articles embodied by SCI, EI, and Medline. He has 3 invention patents. These have widely influenced on lung cancer field in China.

Dr. Richard L. Schilsky is Professor of Medicine and Chief of the Section of Hematology-Oncology at the Department of Medicine at the University of Chicago. An international expert in gastrointestinal malignancies and cancer pharmacology, he has served on a number of peer review and advisory committees for the National Cancer Institute (NCI) including as a member and chair of the NCI Board of Scientific Advisors and as a member of the Clinical and Translational Research Advisory Committee.

Dr. Schilsky earned his M.D. at the University of Chicago Pritzker School of Medicine in 1975. He has previously served as Director of the University of Chicago Cancer Research Center (1991 – 1999) and as Associate Dean for Clinical Research (1999 – 2007). From 1995 – 2010, Dr. Schilsky also served as Chairman of the Cancer and Leukemia Group B, an NCI-sponsored national cancer clinical trials group.

Dr. Schilsky has served as a member of the Board of Directors of the American Society of Clinical Oncology (ASCO) and as ASCO President from 2008 – 2009. He presently serves as a Board member and secretary of the ASCO Conquer Cancer Foundation. He is a member of the external advisory committees of several comprehensive cancer centers including the Roswell Park Cancer Center, the MD Anderson Cancer Center and Tisch Cancer Institute at Mt. Sinai Medical Center.

Dr. Schilsky is Senior Associate Editor of Molecular Oncology, Associate Editor of Clinical Cancer Research and the Journal of the National Cancer Institute and a member of the editorial boards of EMBO Molecular Medicine, Cancer Prevention Research, Cancer Investigation, and Seminars in Oncology, among several other notable journals. He has published more than 290 articles and book chapters in the medical literature and is the editor of four books.

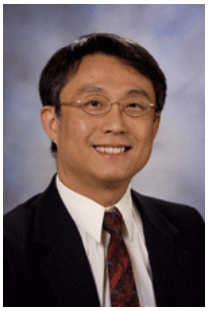
Prof. Patrick G Johnston is Dean of the School of Medicine, Dentistry and Biomedical Sciences and Director of the Institute of Health Sciences at Queen's University Belfast. Prof. Johnston has published over 250 research articles and 5 books, and holds over 25 patents. His research is focused on cellular signaling pathways in human cancer, primarily related to molecular targeted cancer, therapeutics, personalised cancer medicine and mechanisms of drug resistance. He received his medical degree with distinction from University College Dublin in 1982, followed by his PhD in Medicine in 1988. He obtained a fellowship at the National Cancer Institute (NCI USA) in 1987 where he pursued further clinical training in medical oncology and doctoral studies in molecular pharmacology, drug resistance and drug development. He was promoted to Senior Investigator at the NCI in 1991.

In 1997 he moved to Queen's University Belfast as Professor of Oncology and subsequently became Director of the Centre for Cancer Research and Cell Biology in 2004 at the same institution. He has been Dean of the Medical School since 2007. He has been awarded many national and international awards, is a Fellow of the Academy of Medical Sciences, and sits on a number of influential national and international scientific and government advisory boards. He is a Senior Editor of ***The Oncologist***, the official journal of the **Society for Translational Oncology** for which he is Co-Chairman. He is the founder of the biotechnology company, Almac Diagnostics.

Dr. Jin Li is a Professor and Dean of the Department of Medical Oncology at the Fudan University Cancer Hospital, Shanghai. Dr. Li is also the Director of the Clinical Trials Unit at Fudan University Shanghai Cancer Center and the current Secretary General of CSCO.

A practicing physician for the past 29 years, Dr. Li specializes in the treatment of gastrointestinal cancers. He has participated in approximately 100 clinical trials for the treatment of various tumor types including more than 10 global trials since 2004. Dr. Li was lead investigator on 12 Phase I studies, the development of S1 for the treatment of gastrointestinal cancer in China, and the development of an original novel agent (apatinib), which is currently moving forward to Phase III clinical trials.

Dr. Li has been responsible for approximately 12 investigator-initiated research projects including the development of a carcinoembryonic antigen vaccine for the treatment of gastrointestinal cancer, and several translational studies involving biomarker identification through the correlation of clinical response with collected patient specimens and/or pharmacodynamic changes on magnetic resonance imaging. He has published in numerous journals including the European Journal of Cancer, the Journal of Gynecologic and Obstetric Investigations, the Journal of Clinical Gastroenterology and the Chinese Journal of Oncology.



Dr. J. Jack Lee is Professor of Biostatistics and the Kenedy Foundation Chair in Cancer Research at the University of Texas MD Anderson Cancer Center in Houston. He holds joint appointments as Adjunct Professor of Statistics, Rice University; Adjunct Professor of Biostatistics, University of Texas School of Public Health; and Regular Member of the Graduate Faculty, University of Texas Graduate School of Biomedical Sciences.

Dr. Lee has been working on developing and applying innovative biostatistical methodology for translational cancer research. He has particular interests in incorporating multiple biomarkers and implementing Bayesian adaptive designs for more efficient and ethical clinical trials. He is also the lead statistician in many lung cancer and head and neck cancer research projects at MD Anderson and the principal statistician in designing and analyzing the seminal BATTLE trial for targeted agent development in lung cancer.

Dr. Lee is a statistical editor for the *Journal of the National Cancer Institute*, *Clinical Cancer Research* and *Cancer Prevention Research*. He has over 250 publications. Dr. Lee is an elected Fellow of the American Statistical Association.

Dr. Lillian L. Siu is a Senior Staff Medical Oncologist at Princess Margaret Hospital and a Professor of Medicine at the University of Toronto since 2009. Dr. Siu is the Director of the Phase I Program and Co-Director of the Robert and Maggie Bras and Family Drug Development Program at Princess Margaret Hospital. Dr. Siu currently holds a Tier I Cancer Care Ontario Chair in Experimental Therapeutics. She serves on the Board of Directors for the American Society of Clinical Oncology for 2012-2016.

Dr. Siu's major research focus is in the area of new anticancer drug development, particularly with respect to phase I trials and head and neck malignancies. She is the Principal Investigator of a phase I cooperative agreement U01 award (2008-2014) sponsored by the NCI. In addition to her active research in early phase clinical trials, Dr. Siu has been leading genomics initiatives in the area of personalized cancer medicine at the Princess Margaret Hospital. Dr. Siu has extensive interests and experience in the training and mentorship of young oncologists. She has been a member of the Program Committees for both the FECS/ASCO/AACR workshop in Flims, Switzerland and the AACR/ASCO workshop in Vail, Colorado for the past few years, and was one of the course directors for the Flims Workshop in 2009-2011. Internationally, Dr. Siu was the recipient of the US NCI Michaele C. Christian Award in Oncology Drug Development in 2010. Dr. Siu was the Neuroendocrine Tumor Task Force Chair in the North American Gastrointestinal Intergroup Scientific Steering Committee from 2007-9; and she was the ASCO Conquer Cancer Foundation Grants Selection Committee Chair in 2009-10. Dr. Siu was the Chairperson of the AACR Education Committee and Co-Chairperson of the Scientific Committee for the 2012 Annual Meeting. She has published over 160 peer-reviewed manuscripts, and is currently an editor for the *Journal of Clinical Oncology* and *Cancer Discovery.*

Dr. Shun Lu is a professor of Shanghai Chest Hospital, Jiao Tong University. He is Chief of Shanghai Lung Cancer Center. Dr. Lu received his M.D from Shanghai Medical University, Shanghai, China in 1988, and received his PhD from Second Military Medical University, Shanghai, China in 2008. Dr Lu completed his Fellowship of Clinical Oncology in Tel Aviv University, Israel 1996-1997. Dr. Lu was Visiting Professor in the Department of Thoracic/Head and Neck Medical oncology at the University of Texas MD Anderson Cancer in Houston, Texas, USA from 2004-2005. More than 60 of his papers were published in journals such as: Journal of Thoracic Oncology, Chemotherapy, Oncology Reports, Mutagenesis, etc. Dr. Lu is a committee member of numerous associations and societies including Member of ASCO International Affairs Committee (IAC) and MCMC Working Group. He is the member of IASLC membership committee and the associate editor of Journal of Thoracic Oncology. Dr. Lu is a member of Expert Panel State Food and Drug Administration (China), Commissioner of Oncology Society Chinese Medical Association, Vice secretary of Chinese Clinical Oncology Society, Vice Director of Chinese Lung Cancer Study Association, Vice Director of Oncology Society Chinese Medical Association Shanghai Branch. Dr. Lu is the recipient of several awards including "the New Medical Star in Shanghai" in 2002 and in 2004. Dr. Lu studies novel targeted agents and has expertise in lung and other thoracic tumor. He serves as the P.I or CO-P.I of several international clinical trials.

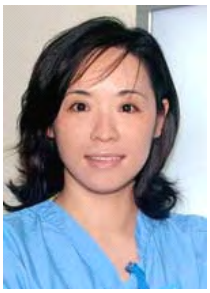
Prof. Tony Mok studied medicine at the University of Alberta in Canada and, following his residency there and fellowship training at Princess Margaret Hospital in Toronto, spent a further 7 years practicing in the fields of oncology and internal medicine. In 1996, Prof Mok moved to Hong Kong after gaining a position as Assistant Professor in the Department of Clinical Oncology at the Chinese University of Hong Kong in Prince of Wales Hospital. In 2007, he was made full Professor within the department and also attained an honorary professorship at the Guangdong Provincial People's Hospital in Guangdong, China and guest professorship at Peking University School of Oncology.

Prof. Mok has published over 130 articles in international peer review journals, including the New England Journal of Medicine, Science, Lancet and Journal of Clinical Oncology. He is also heavily involved in several professional societies and committees, including President-elect of International Association in Study of Lung Cancer, chair of the International Affair Committee and member of publication committee of ASCO, vice secretary of the Chinese Society of Clinical Oncology and chairman of Hong Kong Cancer Therapy Society. In addition, he is the Associate Editor of the Journal of Thoracic Oncology, Clinical Lung Cancer and Asia Pacific Journal of Clinical Oncology and serves on the Editorial Board of Journal of Clinical Oncology and several other major oncology journals. He has presented extensively at various international congresses and is particularly interested in the application of novel therapeutic approaches in the treatment of lung and liver cancer.

Dr. Binghe Xu is Professor and Director of the Breast Cancer Section, Department of Medical Oncology, and Vice Chairman of the Department of Medical Oncology at the Cancer Hospital and Institute, Chinese Academy of Medical Sciences (CAMS), and Peking Union Medical College (PUMC) in Beijing, China He received his Doctorate of Philosophy and Master of Science degree in oncology from the Peking Union Medical College, and his Doctorate of Medicine from Wuhan University Medical College, China.

Dr. Xu has been committed to breast cancer research and clinical trials of new anticancer agents for more than 20 years. His major interests are in basic and clinical research of breast cancer, multidisciplinary cancer treatments, and clinical study of new anticancer agents. Dr. Xu has participated more than 60 clinical trials as PI, currently, he is the executive steering committee (EC) and steering committee (SC) members of several global clinical trials.

Dr. Xu has published 210 papers in peer reviewed oncology journals, including Cancer Research, Journal of Clinical Oncology, Clinical Cancer Research, mainly with respect to breast diseases and clinical trials of anticancer agents. Dr. Xu has served on the editorial boards of 20 journals including The International Journal of Biological Markers, Chinese Journal of Cancer Research, Chinese Journal of Cancer, Experimental Hematology & Oncology. He is a member of several societies, including: Vice Chairman, Chinese Society of Breast Cancer (CSBC); Member of American Society of Clinical Oncology (ASCO); Member of Pharmacopoeia Commission of People's Republic of China (ChPC).



Prof. Ning Liao is the head of Breast Department, Cancer Center, Guangdong General Hospital. She has her M.D., specializes in breast oncology and is a master instructor in South Medical University and Medical College of Shantou University. She pursued her study in the Department of Breast Surgery, National Cancer Center France from 1997 to 1999. She also studied in OHIO, USA in 2003 and in the Department of Breast Cancer Chemotherapy Medicine, School of Medicine, Odense University in 2006. She received Silver and Gold Awards at Asian Cancer Congress respectively in the year of 2010 and 2011. Prof. Liao especially focuses on the clinical practice in Breast Cancer. She specializes in early diagnosis of 1mm breast cancer, breast conserving surgery, minimally invasive surgery and breast reconstruction surgery etc. She is an expert at using the latest research results to guide clinical cures and carry out the best individualized treatment.

Dr. Martin J. Murphy. Jr has four decades of healthcare and cancer research, extensive experience as a peer-reviewed cancer scientist, is a Professor of Medicine, editor and oncology consultant. Dr. Murphy, a graduate of New York University, was awarded postdoctoral fellowships at the Institut de Pathologie Cellulaire, Paris, France, the Patterson Laboratories of the Christie Hospital and Holt Radium Institute, Manchester, UK, and the John Curtin School of Medical Research, Australian National University, Canberra, Australia. He was on the faculty of St. Jude Children's Research Hospital, Memphis, TN, Memorial Sloan-Kettering Cancer Center, New York, NY and Wright State University School of Medicine, Dayton, OH. Dr. Murphy founded the Hipple Cancer Research Center in 1977 and led it for the next two decades as its chief executive officer. Endeavouring to advance new discoveries and enhance improved global healthcare delivery, Dr. Murphy founded AlphaMed Consulting, and for more than fifteen years has provided support for comprehensive cancer centres as well as selected cancer research-intensive pharmaceutical and biotech companies.
Dr. Murphy is convener of **ACT China**, the **Society for Translational Oncology**, and member of the National Cancer Policy Forum of The Institute of Medicine (IOM) of the National Academy of Sciences in the US. He is chairman of The Conquer Cancer Foundation of the American Society of Clinical Oncology, a director of the Foundation for the National Institutes of Health, and a charter member and director of C-Change founded by former President George H. W. Bush and former First Lady Barbara Bush. Dr. Murphy is founding chief executive officer of the CEO Roundtable on Cancer, established in 2001 at the request of former President George H.W. Bush. He and Ann Murphy, PhD, were married in 1965; they have five children and 10 grandchildren.

Ethical considerations in cancer clinical trials

Patrick G. Johnston

Ethical considerations have been part of the conduct of studies with humans for several decades. However, it is only since WW II and several abusive trial situations that came to attention that ethical considerations have become a prominent and critical part of the conduct of clinical trials both for safety and well-being of the subjects or volunteers enrolled in these studies.

The overarching objective of clinical research is to develop knowledge to improve health and/or increase understanding of human biology. Subjects who participate are the means to securing such knowledge. By placing some people at risk of harm for the good of others, clinical research has the potential for exploitation of human subjects. Ethical requirements for clinical research aim to minimize the possibility of exploitation by ensuring that research subjects are not merely used but are treated with respect while they contribute to the social good.

For the past 50 years, the main sources of guidance on the ethical conduct of clinical research have been the Nuremberg Code, Declaration of Helsinki, Belmont Report, and the International Ethical Guidelines for Biomedical Research Involving Human Subjects and similar documents (1-4). However, many of these documents were written in response to specific events and to avoid future scandals. By focusing on the instigating issues, these guidelines tend to emphasize certain ethical requirements while omitting others.

Ethical considerations have a multiplicity of roles during the conduct of clinical trials (5). These roles span a broad range—from matters related to the design of a study to the conduct and even to the reporting of the results obtained. Each of these roles needs to be carefully considered and explained in the context of international and national principles and guidelines. It is also very important, in those jurisdictions where well established governance of ethics committees is in place, to conform to the principles, laws, guidance, and processes that have been prescribed.

My talk will focus on a number of these key ethical requirements that must adopted for the health, economic, cultural settings in which clinical research is to be undertaken.

References: *1. Not available. The Nuremberg Code. JAMA.1996;276:1691 2. World Medical Association. Declaration of Helsinki. JAMA.1997;277:925-926. 3. National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research. the Belmont Report, Washington, DC: US. 4. Council for International Organisations of Medical Sciences. International Ethical Guidelines for Biomedical Research Involving Human Subjects. Geneva, Switzerland: CIOMS; 1993. 5. Ezekiel et al. JAMA 283 27101-11 2-000*

Phase I clinical trials: objectives, design, and endpoints

Lillian L. Siu

Phase I clinical trials represent the first evaluation of a new drug or drug combination in humans and lay the foundation for a successful drug development process. The primary objective of Phase I trials is to define drug safety, tolerability and dose-limiting toxicities (DLT) in order to recommend an appropriate dose for subsequent Phase II trials (recommended Phase II dose [RPTD]). The secondary objectives are to characterize the pharmacology of the drug including pharmacokinetics (PK) and pharmacodynamics (PD) and to examine for preliminary evidence of antitumor activity. In this session, the fundamental elements of Phase I trials will be discussed, including selection of a starting dose and eligibility criteria. While the key guiding principle behind each of these Phase I trial elements remains focused on defining the safety of a new drug or drug combination, the emergence of the molecularly targeted era has led to specific considerations and these will be highlighted using examples. An overview of rule-based versus model-based dose escalation schemes, as well as their advantages versus limitations will be presented. The utilization of expansion cohorts to identify target patient populations of interest and/or to perform PD studies to demonstrate target engagement will be discussed. Phase I trial of drug combinations can be complex and thus will only be briefly described. At the end of this session, the participants should be familiarized with the basic concepts of Phase I trials and also appreciate some of the evolving complexities with dose-finding evaluations in early drug development.

Key Messages

- The primary objective of Phase I trials is to define a safe and tolerable dose of a new drug or drug combination that is appropriate for subsequent Phase II evaluation. Typically a pre-specified frequency of DLT is accepted and this specification helps to estimate the RPTD.
- Secondary objectives are to characterize pharmacology (what the body is doing to the drug = PK; and what the drug is doing to the body = PD) and preliminary antitumor activity.
- Rule-based and model-based dose escalation methods exist with relative advantages and limitations to derive at the RPTD. The underlying principle is consistent with any dose escalation methods: starting dose should be safe, escalate rapidly in absence of toxicity and escalate conservatively in presence of toxicity, minimize patients at low, potentially sub-therapeutic dose levels and treat more patients at higher, tolerable and potentially more therapeutic doses.
- The emergence of molecularly targeted agents has led to specific considerations for many elements such as eligibility criteria and definition of DLT in Phase I trials because of their on-target and off-target effects.

References: *1. Adjei AA. J Clin Oncol 2006;24(25):4054-55. 2. Agrawal M & Emanuel EJ. JAMA 2003;290:1075-82. 3. Eisenhauer EA, et al. J Clin Oncol 2000;18:684-92. 4. Horstmann E, et al. N Engl J Med 2005;352:895-904. 5. Ivy SP, et al. Clin Cancer Res 2010;16:1726-36. 6. Korn EL, et al. J Clin Oncol 2001;19:265-72. 7. Le Tourneau C, et al. J Natl Cancer Inst 2009;101:1-13. 8. Parulekar WR & Eisenhauer EA. J*

Natl Cancer Inst 2004;96:990-97. 9. Roberts TG, et al. JAMA 2004;292:2130-40. 10. Simon R, et al. J Natl Cancer Inst 1997;89:1138-47.

Pharmacokinetics, pharmacodynamics, and identifying adverse events in Phase I clinical trials

Lillian L. Siu

The collection, analysis and correlation of pharmacokinetic (PK), pharmacodynamic (PD) and safety data in Phase I clinical trials enables the comprehensive characterization of the pharmacologic and biologic properties of a new drug or drug combination. There are many ways in which PK results can contribute to the development of a new drug: i) stop dose escalation due to PK futility; ii) assist with dosing schedule determination; iii) help to explain toxicities encountered and/or PD effects observed; and iv) provide drug-drug interaction information. In Phase I trials, the conduct of correlative studies (such as assaying for PD effects in paired fresh tumor biopsies procured before treatment and during treatment) can provide guidance on the optimal biological dose especially if limited toxic effects are encountered during dose-finding. Furthermore, with an increasing number of compounds entering first-in-human testing, there are emerging interests and growing demands to demonstrate proof-of-mechanism (e.g. tumor shrinkage, stabilization of previously growing disease, target engagement in tumor tissues) as early as possible, e.g. at the completion of Phase I trials, such that agents with limited potential to ever succeed will be discontinued from further development. In Phase I trials, given the heterogeneity of the patient population enrolled, the lack of a control group, and the variability in drug dose or schedule among patients, it is not possible to validate the value of predictive biomarkers to identify those most likely to respond. However, the evaluation of companion diagnostic biomarkers that accompany the development of a new drug should begin from preclinical and early trial phases and may ultimately expedite its overall duration from first-in-man testing to approval. For safety assessments, standard terminology criteria for grading of adverse events exist to promote medical accuracy and consistency in data sharing and reporting. Toxicity pattern recognition and the careful assessment of acute toxicity in Phase I trials by experienced clinical teams help inform important safety signals with novel agents. The limitations of Phase I trials in capturing rare, late or cumulative toxicities will be discussed.

Key Messages

- PK parameters such as peak concentration (Cmax), exposure (area under time x concentration curve), half-life, clearance, etc. provide information about a drug’s pharmacologic properties. PK evaluations in Phase I trials provide the opportunity to optimize dosing schedule, understand drug-drug interactions and explain toxicity and PD effects observed.
- PD biomarkers provide information about the mechanistic effect of a therapeutic intervention on the patient and/or tumor.

- Predictive biomarkers cannot be validated in Phase I trials but the development of companion diagnostic biomarkers should occur early on to help elucidate the efficacy and/or safety of a specific drug for a targeted patient group or subgroups.
- Phase I trials provide the first evaluation of the safety profile of a new drug and it is important for experienced clinical teams to recognize toxicity patterns, perform careful assessments and report using standardized terminology criteria.

References: *1. Abdel-Rahman SM & Kauffman RE. Annu Rev Pharmacol Toxicol 2004;44:111-36. 2. Biomarkers Definitions Working Group. Clin Pharmacol Ther 2001;69:89-95. 3. US Department of Health and Human Services. Common Terminology Criteria for Adverse Events (CTCAE) Version 4.03. 2010. Available at: http://evs.nci.nih.gov/ftp1/CTCAE/CTCAE_4.03_2010-06-14_QuickReference_8.5x11.pdf (accessed October, 2011). 4. Dancey JE, et al. Clin Cancer Res 2010;16:1745-55. 5. Eisenhauer EA, et al. Eur J Cancer 2009;45:228-47. 6. Postel-Vinay S, et al. J Clin Oncol 2011;29:1728-35. 7. Undevia SD, et al. Nat Rev Cancer 2005;5:447-58.*

The principal investigator’s responsibilities in conducting clinical trials

Richard L. Schilsky

This presentation will summarize the responsibilities of the principal investigator (PI) of a clinical trial. Types of human subjects research will be reviewed and a definition for ‘clinical trial’ will be provided. The key elements of Good Clinical Practice (GCP) that specify the responsibilities of a study PI will also be reviewed. Foremost among these is that the PI is responsible for the overall conduct of the study, including: interactions with regulatory agencies, financial and regulatory aspects of the contract and/or grant that support the study, modifications to the original protocol submission, Institutional Review Board correspondence, other regulatory agency correspondence and the recruitment, training and supervision of the team running the trial. The PI may or may not also function as the sponsor of the study. The study sponsor is responsible for implementing and maintaining quality assurance for the trial in compliance with the protocol, GCP and regulatory requirements. These include developing the investigational plan, the manufacture and labeling of investigational products, obtaining regulatory approval before the study begins, initiating, suspending, or terminating the study as required and refraining from commercialization of the investigational product until regulatory approval is obtained. Quality assurance and managing potential conflicts of interest are essential to ensure the integrity of the trial and to maintain the public trust in the study results.
The study PI should have access to all raw study data and should be independent in the analysis, interpretation and reporting of the study results.

Key Messages

- Compliance with international standards for GCP provides the foundation for effective and ethical conduct of clinical trials.
- The PI may delegate responsibilities to trained and qualified members of the research team but retains ultimate responsibility for all aspects of study conduct.
- Study monitoring is the act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, GCP, and the applicable regulatory requirements. Study auditing is a systematic and independent examination of trial related activities and documents to determine whether they adhere to the protocol, GCP, and the applicable regulatory requirements.
- The PI should have full access to the raw study data and control over how the data are analyzed and reported.
- Disclosure of financial or other interests, which might be construed as resulting in an actual, potential, or apparent conflict, is important to maintain the confidence of physicians, patients and the general public in the integrity of clinical cancer research.

Objectives, design considerations, and endpoint selection for phase II clinical trials

Richard L. Schilsky

Phase II clinical trials are an essential aspect of drug development that enables the "go-no go" decision to be made in order to advance a new agent to Phase III testing. The primary goals of Phase II trials are to estimate drug activity, describe toxicity, develop pharmacokinetic-pharmacodynamic (PK-PD) correlations, and confirm drug target interactions. This presentation will review the essential elements of a Phase II trial including development of the primary objective and selection of the primary study endpoint, choice of the study population and description of the intervention to be studied. With the increasing number of targeted agents in clinical development, there is increasing use of time to event endpoints in Phase II clinical trials. The pros and cons of such endpoints will be described. Controversy exists regarding the relative merits of single arm and randomized Phase II trial designs.

Examples of such designs will be provided and the circumstances in which each type of trial might be preferred will be described. Enrichment designs, such as biomarker-driven clinical trials and the randomized discontinuation design, provide opportunities to enrich the study population with individuals most likely to benefit from the treatment or to display the endpoint of interest. The merits and liabilities of such study designs will be described. At the conclusion of this presentation, participants should have an in-depth understanding of the design options for Phase II trials and should be able to select the optimal design based on the characteristics of the drug being studied, the clinical hypothesis being evaluated and the patient population being enrolled.

Key Messages

- The goals of Phase II trials are to estimate activity, describe toxicity, develop PK-PD correlations and confirm drug-target interactions.
- The optimal trial design will depend on the patient population being studied, the primary endpoint selected, the level of activity of interest, the precision of the estimate of activity.
- Assessment of disease progression depends on definition of progression and extent and frequency of evaluation but is always an estimate as true progression occurs between observations.
- Randomized Phase II designs reduce selection bias, improve patient comparability, and are generally preferred for progression-based endpoints and when historical data are unavailable or unreliable.

References: *1. Zia, MI et al. J Clin Oncol 2005;23:6982-6991. 2. Sharma, et al., JNCI 2011;103:109.3 3. Niho et al. J Clin Oncol 2006. 4. Ratain et al. J Clin Oncol 2006. 5. Gan et al. J Clin Oncol 2010;28(15):2641-2647. 6. Rubinstein L, Crowley J, Ivy P, et al. Clin Cancer Res 2009;15:1883-1890. 7. El-Maraghi RH, Eisenhauer EA. J Clin Oncol 2008;26:1346-1354. 8. Betensky RA, Louis DN, Cairncross JG J Clin Oncol 2002;20:2495-2499. 9. Michaelis LC, Ratain MJ. Clin Cancer Res. 2007;13(8):2400 – 2405. 10. Vickers AJ, Ballen V, Scher HI. Clin Cancer Res 2007;13(3):972 – 976. 11. Karrison TG, Maitland ML, Stadler WM, et al. J Natl Cancer Inst. 2007;99(19):1455 – 1461. 12. Seymour L, Ivy SP, Sargent D, et al. Clin Cancer Res. 2010;16(6):1764 – 1769.*

Statistical considerations for phase II trials and adaptive designs

J. Jack Lee

The primary objectives of Phase II studies are to provide an initial assessment of a drug's efficacy (Phase IIA), refine a drug's toxicity profile, and compare efficacy among active agents to send the most promising one(s) to Phase III trials (Phase IIB). After the toxicity profile of an anticancer treatment is determined, Phase II studies are conducted to evaluate whether the new agent has sufficient anticancer activity to warrant further development. Statistical properties of clinical trial designs including Type I and Type II errors, P value, and Bayesian paradigm are briefly reviewed.

Typically, a Phase IIA trial is a single-arm, multi-stage study with a goal to screen out ineffective drugs. A sample size can range from 30 to 60 patients. The primary endpoint is often the clinical response. Commonly used designs include Gehan's design, Simon's two-stage designs, and other multi-stage designs, etc. In addition, Bryant and Day's two-stage design monitors efficacy and toxicity simultaneously. Lee and Liu's predictive probability design allows continuous monitoring to increase the efficiency, flexibility, and robustness of trial conduct.

If an agent passes the Phase IIA evaluation, the subsequent Phase IIB trial is often a randomized, multi-arm study comparing effective treatments with a goal of identifying the most promising treatment regimen to evaluate further in a Phase III trial. The challenge is to choose the most promising regimens among a large number of potentially active regimens for further development. In a review of randomized Phase II studies, Lee and Feng found that many studies applied randomization to achieve patient comparability, while embedding a one-sample Phase II design within each treatment arm. Due to limited sample sizes, such designs typically do not yield sufficient statistical power for a strict head-to-head comparison between treatment arms. Simon, Wittes and Ellenberg's pick-the-winner design has also been used. However, this ranking and selection procedure controls only Type II errors. As a result, the false positive rate can be high. Randomized discontinuation design is suitable for cytostatic agents without known biomarkers. Seamless Phase II/III design speeds up the drug development by eliminating the "white space" between the two phases.

Randomized Phase IIB studies are often designed with a moderate sample size (e.g. 50 to 200), a medium study duration (e.g. one to three years), and Type I and Type II error rates of 10% to 20%. A false positive result is of less concern because the final verdict of the effectiveness of a regimen can be provided in a Phase III evaluation. In addition, in order to shorten the study duration, earlier endpoints such as time-to-recurrence, disease-free survival, or time-to-progression are commonly employed in Phase IIB settings. A moderate to large expected difference is often assumed for Phase II studies. Bayesian adaptive designs are useful for learning and discovery. Response adaptive randomization, early stopping for futility and/or efficacy, add/drop agents are the most important features for adaptation. An example of the BATTLE trial in the development of targeted agents for personalized medicine in lung cancer is given.

Key Messages

- Single-arm Phase IIA trials provide an effective way to assess the initial efficacy of new treatments.
- Multi-stage designs increase the study efficiency while the predictive probability design is more flexible.
- Pick-the-winner designs do not control Type I error.
- Interim monitoring and early stopping for futility of efficacy is desirable.
- Adaptive randomization enhances the study's individual ethics.

Statistical considerations for phase III randomized trials, interim analysis, and data monitoring

J. Jack Lee

Phase III trials are considered definitive trials for comparing a new treatment with a standard treatment in a rigorous manner, e.g. a double-blinded, randomized, placebo-controlled study. The goal is to define the best treatment, which implies a possible change in the current standard practice. Typically, stringent statistical requirements such as a two-sided 5% type I error rate and at least 80% power are required. The primary endpoint is often the overall survival rate. A phase III study requires hundreds of patients (in cancer treatment trials) or even thousands or tens of thousands of patients (in primary prevention trials). Generally speaking, a phase III trial tends to be a multi-centre study with several years of accrual and follow-up, and is therefore quite costly. Due to the size and study duration, formal interim analyses, such as the group sequential methods by Pocock, O'Brien-Fleming, Peto, or Lan-Demets are often employed to assess early stopping needs due to efficacy, futility, or both. Compared to phase I or phase II studies, where only the evaluable patients are included in the analysis, most phase III studies employ the intent-to-treat (ITT) principle in the data analyses.

In an effort to standardize the design, conduct, and reporting of clinical trials by integrating inputs from government (regulatory authority), industry, and academia, the International Conference on Harmonization has issued guidelines (ICH E9) on the statistical principles of clinical trials. The ICH consortium encompasses three main regions: Europe, Japan and the U.S.A. The guideline is quite comprehensive and can serve as a template for protocol development, study conduct, data analysis, and final reporting.

To ensure the safety of patients participating in clinical trials, every clinical trial must be approved by a local institutional review board (IRB) at its inception and on an annual basis. An IRB typically consists of internal and external clinical trial experts, as well as community representatives. Every trial must have a sound scientific and ethical justification. In addition to the IRB's oversight, most randomized clinical trials must also be monitored by a data monitoring committee (DMC) or a data safety monitoring board (DSMB). The main function of such groups is to monitor patient accrual and safety, and treatment efficacy for each clinical trial. For double-blinded studies, the DMC can ask the study statistician to provide unblinded data in a closed session. The integrity of each study can be preserved through independent reviews by the DMC. Recommendations for early stopping due to toxicity, futility or efficacy can be made by the DMC and communicated to the study investigators and regulatory bodies.

Standard statistical reports, including descriptive and summary statistics, should be provided for the review of each study on at least an annual basis. Event charts, such as a calendar event chart and an interval event chart, are useful graphical tools to track and plot multiple timed event data at the individual level. They are complementary to the commonly used Kaplan-Meier survival plots, which provide a summary for the grouped data. They are highly

effective for monitoring patient accrual and scheduling in the conduct of clinical trials.

The results from a clinical trial should be published upon completion of the trial, regardless of whether the results are positive or negative. To standardize the report of randomized clinical trials in the literature, the consolidated standards of reporting trials (CONSORT) group proposed that all clinical trials should be summarized according to CONSORT guidelines. The number of patients registered and randomized into a trial, as well as the follow-up status over time can be easily shown in a CONSORT diagram.

Key Messages

- Phase III trials are definitive trials for comparing a new treatment with a standard treatment in a rigorous manner. The goal is to define the best treatment with a potential to change in the standard practice.
- Phase III trials are often double-blinded, randomized, placebo-controlled studies. Most phase III studies employ the intent-to-treat (ITT) principle in the data analyses.
- Interim monitoring of efficacy is essential for large Phase III trials. Group sequential methods can be applied to assess the interim treatment efficacy. The trial can be stopped early due to efficacy, futility, or both
- Data monitoring committee provides an objective evaluation of the interim data.
- Event charts are useful graphical tools to track and plot multiple timed event data at the individual level.
- The results from a clinical trial should be published upon completion of the trial, regardless of whether the results are positive or negative. The CONSORT diagram should be used to report the number of patients registered and randomized into a trial, as well as the follow-up status over time.

Colorectal cancer opportunities and challenges

Patrick G. Johnston

Colorectal cancer is the second most prevalent cause of cancer-related death in the Western world. Approximately 75% of patients with colorectal cancer present with locally advanced disease; despite curative surgery, around 40% of patients still experience disease recurrence leading to morbidity and eventual mortality. In 2008, there were an estimated 39,991 and 334,000 new cases of colorectal cancer in the UK and in the European Union respectively, and worldwide an estimated 1.24 million new cases of colorectal cancer were diagnosed in that year. Colorectal cancer is the third most common cancer in men (10.0% of total) and the second in women (9.4% of the total). Colorectal cancer affects over 35,000 people in the UK each year, and the number of new cases is increasing. In the post-operative setting, there is clear evidence that adjuvant chemotherapy significantly improves clinical outcomes for patients with stage III colorectal cancer. Chemotherapeutic drugs such as 5-FU, oxaliplatin, and irinotecan are now used as part of standard care in the advanced setting, and the arsenal of

new therapies with significant activity in the advanced disease setting, such as the VEGF inhibitors (Avastin) and EGFR inhibitors (cetuximab, panitumumab), is steadily growing. Nonetheless the management of patients with potentially curable stage II and stage III disease remains an active area of clinical debate, as the overall combined five year survival for these patients remains around 65%. Indeed, only one third of patients who are at risk of relapse derive any significant benefit from adjuvant therapy, and thus one of the major remaining issues is to define which patient subsets really benefit from treatment with chemotherapy. (1)

In the metastatic disease setting, combinations of 5-FU with irinotecan and oxaliplatin, alongside VEGF inhibitors such as bevacizumab and EGFR inhibitors, have now enhanced response rates to approximately 50%-60% with significant, but modest, improvements in overall survival. However, the recent advances in the use of 'biologics' in the metastatic disease setting have not translated into any clinical benefit in the adjuvant setting. Therefore, while the therapeutic repertoire for patients with advanced colorectal cancer has now expanded to the point where there are many more choices in terms of treatment, it is not straightforward to translate clinical paradigms from the metastatic to the adjuvant disease setting. In addition, half of the patients who undergo chemotherapy and biologic therapy for metastatic colorectal cancer derive no benefit. With the increasing number of therapeutic options, predictive marker testing and companion biomarker development have begun to play a role and will become increasingly important over the coming years. This has the potential to improve the overall response rates and survival outcomes and prevent unnecessarily exposing patients to toxic effects of drugs from which they are unlikely to benefit. With the development of microarray technology and next generation sequencing (NGS), a number of investigators have begun to examine the potential of global gene expression profiling, single nucleotide variants (SNVs), small insertions/deletions (indels), and DNA copy number alterations to molecularly characterise specific patient subsets. (2)

My talk will address these current challenges and how we might begin to implement them into patient care.

References: *1. Johnston PG, Lawler M. Expert opinion: Future frontiers and challenges in cancer medicine. The Oncologist: 17: 3-5. 2012. 2. Schaeybroeck S, Allen WL, Turkington RC, Johnston PG. Implementing prognostic and predictive biomarkers in CRC clinical trials. Nat Rev Clin Oncol 8: 222-32, 2011.*

1. General Information

1.1 Arrival and Departure

Operating Time: 29-30 Nov. and 2 Dec.

Kayi Conference will provide arrival service at Guangzhou Baiyun International Airport and Guangzhou East Railway Station from November 29, 2012 to November 30, 2012, and will arrange the transport to the Vanburgh Hotel. Upon the conclusion of the meetings, transportation will be provided to the delegates from the hotel to the airport or the railway station on December 2, 2012.

Should there be any change of your departure information, please inform STO/CSCO or Kayi Conference Staff for transport arrangement to the ports.

1.2 Registration & Information

Location: Lobby of Vanburgh Hotel

Registration time:	November 29	08:00 - 21:00
	November 30	08:00 - 10:00

Upon arrival, delegates shall go to the Registration & Information Desk with their passport or ID card to complete the registration procedures, collect their accreditation card and a package of materials for the meetings, and check in.

The Registration & Information Desk also provides information services such as Meetings' Programme, catering, and accommodation. A Social Programme is available for those who wish to join in the sightseeing tour in Huacheng Square after the gala dinner on 1 December, 2012.

Social Programme Information：

- Available for: All participating delegates
- Programme：

Dates	Routes
December 1 (Saturday)	Huacheng Square

- Application Deadline:
- To take part in the Programme on December 1, please hand in the application information before 10:00, November 30.

1.3 Accommodation

All delegates attending the Meetings will be accommodated at the Vanburgh Hotel. Incidental charges in the hotel such as laundry, direct call, mini bar and any other charges, and accommodation and catering for any extended stay will be borne by delegates themselves.

- Vanburgh Hotel:
  Address: 126 Huangpu Dadao West, Guangzhou, P.R.C. 510623
  Telephone: (86-20) 38683868 Fax: (86-20) 38683388
  Email Address: info@vanbugh.com
  Website: www.vanburgh.com

Hotel facilities and available services at delegates expense:

Items	Name	Location
Recreational Facilities	Spa	4th Floor 5th Floor
	Massage & Foot Massage	
	Hair Salon	
	Swimming Pool at an alfresco garden	
	Fitness Room	
	Mah-jong Room	
	Leisure Bar	
Restaurants & Bars	Wanhin (Chinese Restaurant)	3rd Floor
	The Stage (Western Restaurant)	1st Floor
	Ripple Bar	
Business Center	1st Floor	

1.4 Catering

Regular Meals

Breakfast: Wan Hin Restaurant, 3rd Floor; Lunch & Dinner: Wan Hin Restaurant, 3rd Floor

* Note: The delegates are kindly requested to present their accreditation cards when entering into the dining facility.

Official Functions

Date & Time	Function	Venue	Format	Attire
December 1 (Saturday) 19:30-21:30	Gala Banquet hosted by CSCO	Bingsheng Restaurant	Table dinner	Formal

Contact Person	CSCO	Kayi	Kayi	Kayi
	Wang Lei	Sharon Li	Fay Mo	Yang Zheng
Contact Number	13681064315	13924076739	13570592329	13560342945

2. About Guangzhou

2.1 Weather and Climate

Guangzhou, located at 112 degrees 57 minutes to114 degrees 03 minutes east longitude, 22 degrees 35 minutes -23 degrees 35 minutes north latitude, is a subtropical monsoon climate zone.

Weather Forecast

Date	29 Nov.	30 Nov.	1 Dec.	2 Dec.
Night				
Day Time				
Highest Temp (°C)	17℃	17℃	17℃	18℃
Lowest Temp (°C)	13℃	14℃	14℃	13℃
Wind	Breeze	Breeze	Breeze	Breeze

2.2 Local Time

Standard Time Zone: GMT/UTC + 08:00 hour

2.3 Language

Mandarin Chinese and Cantonese are the prevailing languages spoken in Guangzhou. The official language of ACT China is English.

2.4 Electricity and Voltage

The standard voltage for residential use is a single-phase AC, 220V/50HZ.

2.5 Currency and Credit Cards

The Yuan, also called renminbi (RMB), is the local unit of currency and all banks in Guangzhou provide RMB exchange services. Most business in China now accept international credit cards including MasterCard, Visa, American Express and JCB.

2.6 Useful Telephone Numbers

- Police: 110
- Fire: 119
- First Aid: 120
- Check Telephone Number: 114
- Taxi：96900

Notes

Notes

Notes

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