关于成立 CBA 生物标记物与伴随诊断研讨小组的倡议书

精准医疗是当前全球生物医学界关注的热点领域，也是医学发展大势所趋，主要包括精准预防、诊断、治疗与预后四个层面。精准医疗的核心是让患者得到准确有效的治疗，重获新生并提高生活质量。随着以肿瘤分子靶向治疗为代表的个体化医学的推广，精准医疗逐渐成为肿瘤治疗的新方向。精准诊断是精准医疗的基础，从健康人群的筛查、疾病的早期诊断和预后、指导治疗的伴随诊断以及检测复发等方面，在不同环节中都发挥极其重要的作用。生物标志物的广泛应用，结合基因组、蛋白组和代谢组信息的大数据为基础的数字病理和人工智能，将推动精准诊断的新发展。不久的将来，我们相信将是精准诊断的全面崛起和高速发展的时机。本小组的创立就是为了布局和代表未来医学诊疗的发展方向。

CBA 作为一个促进中美医药产业交流和合作的专业团体，依托大华府地区的政治、经济、学术、科研、人才，地理优势，现在正式成立生物标志物和伴随诊断研讨小组。我们的宗旨是加强生物标记物和伴随诊断的科学研讨，促进本领域专家以及其他感兴趣专业人士的交流和合作。

此小组活动的核心基于关注和探讨精准医疗方面诊断和标记物的科研发展， 技术更新，临床试验与应用，策略指南变化更新，HEOR 探讨及监管章程变化与进展。我们预计召集 15-20 名热衷于此领域的 CBA 现职个人会员，终身会员和企业会员。小组成员每月与会一到两次， 讨论与以上所列项目有关的具有代表性的实例。 比如分析突出的最新发表的科研文章， 指南， 策略，科研大会热点，等等。 此外， 小组还将为 CBA 活动提供诊断和标记物方面的建议并参与筹划。本小组成立后，计划提交 CBA 此小组年初计划及年终汇报，以为后期发展打下良好基础。

本小组所有的运行，管理，发展都遵循 CBA 的章程、使命和原则， 特别是小组所有成员严格遵守关于知识产权方面的所有法律法规。

生物标记物和伴随诊断研讨小组倡议人：

杨宏钧（Harry Yang）， 余红（Judy Yu）， 朱沛轩（Peixuan Zhu）， 邢传华（Julia Xing）

CBA is establishing a Biomarker and Companion Diagnostics Study Group: Open to CBA Active, Lifetime, and industry sponsor members.

Precision medicine is a focal point of attention worldwide and the future of medicine. It involves precision prevention, companion/complementary diagnostics, targeted treatment and prognosis. The essence of precision medicine is to treat the right patient, with the right drug, at the right time, in order to improve the effectiveness of the treatment with minimal side effects, and to improve quality of life for the patients. Along with the progress of molecular-targeted cancer therapy, biomarker and companion/complementary diagnostics has become a new area of importance and rapid growth. Precise diagnosis is the foundation of precision medicine. It plays an instrumental role in various aspects from screening of healthy people, early diagnosis and prognosis of diseases, to aiding optimal targeted treatment decisions, and monitoring for recurrence, etc. The widespread use of biomarkers, combined with the digital pathology and artificial intelligence based on big data on genomic, proteomic and metabolomics information, will drive new developments in precision diagnostics. We believe it will be soon the prime time for the rapid development of precision diagnostics. This group therefore is established to strategize and represent the future direction of medicine.

CBA's mission is to bridge biopharmaceutics between US and China, utilizing the political, economic, academic, research, talents and geographic advantages in the greater Washington DC region. It is proposing the formation of the Biomarker and Diagnostic Study Group. The main purpose of this group is to strengthen and advance scientific discussion and communication in area of biomarker and companion/complementary diagnostics among the experts, interested members, and the Biopharmaceutical community.

The activities of this group will mainly focus on research advancements, technology improvements, clinical trial development, guideline updates, HEOR studies, and regulatory policy changes in area of biomarker and companion/complementary diagnostics related to precision medicine. We plan to enlist 15-20 CBA active members (personal, industrial, and life time) to participate, meeting up to 2 times a month to discuss and explore representative events related to the above topics. For example, discussions may include the review of key publications, guidelines, polices, and hot topics of key conferences. In addition, the group may also provide recommendations and participate in planning of CBA organizational level events and annual meetings. Once formed, the group plans to provide CBA with its annual activity plan and end-of-year report, in order to facilitate future development of this group.

This group will obey all CBA operational, management, and development policies, principles and mission, especially strictly follow intellectual property policy and regulations.

Organizing Committee Members:

杨宏钧（Harry Yang），余红（Judy Yu），朱培轩（Peixuan Zhu），邢传华（Julia Xing）

Hongjun Yang, PhD

- Currently Dr. Yang is an Executive Precision Medicine Strategic Leader at Precision Medicine & Genomics division of IMED department, AstraZeneca Pharmaceuticalsin with the strengths in policy making, regulatory compliance and innovative research and development.
- Also serves as a co-chairman of guidance committee of Precision Medicine & Companion Diagnostics in China Society of Biotechnology.
- Scientific and technical expert in multidisciplinary areas, original developer for electrochemiluminescence technology that led to the commercialization of the fourth generation of signal detection in diagnostics and also to the first author paper published in Nature/Biotechnology in February 1994.
- With fifty years working experience, research interests covered Physics, Chemistry, Mathematics, Biology, Pharmaceutical and Computer Science, etc. Dr. yang has served as an executive leader or/and co-founder for Genomitrix, Nanogen, Gene Logic, MetriGenix, National Center for Biochip Technology at Shanghai, Tianjin Biochip company, Sirnaomics, Suzhou Sirnaomics, Shanghai Clinical Research Center, Shanghai Jiao Tong University and AstraZeneca, etc.; a visiting professor for Virginia Commonwealth University, Shanghai Jiao Tong University, and Japan Waseda University; and a consultant for Roche Diagnostics, Mitsubishi and Samsung, etc.

Biographical Sketch

Judy Yu, Ph.D.
Director, Medical Diagnostics
US Medical Affairs,
Oncology Business Unit
AstraZeneca

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	FIELD OF STUDY
Peking University, Beijing, China	BS	Chemistry
University of Minnesota, Duluth, MN	MS	Chemistry
Carnegie Mellon University, Pittsburgh, PA	PhD	Chemistry (Biochemistry Biophysics Interdisciplinary Program)

EXPERIENCE

Dr. Judy Yu is currently a medical diagnostic director with AstraZeneca Oncology Business Unit. She is responsible for the development and execution of US oncology companion diagnostic medical strategy to minimize testing barriers to therapy, and optimize testing pathways. She also conducts internal and external educational programs to all stakeholders in oncology precision medicine, as well as evidence generation to support oncology product portfolio strategy. Prior to AstraZeneca, she worked as a global marketing leader at Becton Dickinson in charge of global product marketing strategies, brand and portfolio life cycle management. She spent most of her career at Abbott Molecular right after graduate school, and held various positions as a diagnostic assay development scientist in R&D and scientific affairs director in global marketing. Dr. Yu has conducted several large scale worldwide studies to evaluate molecular diagnostic assays, and to demonstrate clinical utility and validity, analytical and clinical performance characteristics, and practical parameters (time-motion, workflow, throughput) of diagnostic assays. She not only has extensive experience in developing and evaluating new molecular technologies, searching for cancer biomarkers, and but also spent more than 15yrs working with clinical opinion leaders in practice and professional organizations establishing the utility and applications of new molecular diagnostic tools.

Dr. Yu has been active in various professional organizations. She served on the board of directors for American College of Medical Genetics and Genomics Foundation, and has been a member of:

American College of Medical Genetics and Genomics (ACMG)

Member of Association of Molecular Pathologists (AMP)

American Society of Microbiology (ASM)

Chuanhua Julia Xing, Ph.D.

Dr. Chuanhua Julia Xing is the founder of XPrecision LLC and ShiHua Big Data Healthcare (Shenzhen, China), focusing on the development of artificial intelligence products with applications to disease prediction, diagnosis, treatment and management and drug development. She is also Vice President and board member of Chinese Biopharmaceutical Association, visiting professor of Sun Yat-Sun University, member of Precision Medicine Advisor Committee for Beijing Health Promotion Association etc. She also serves as organizers or chairs to meetings and organizations such as the Joint Statistical Meetings and the Committee on Nominations for Caucus for Women in Statistics, American Association of Statistics. She graduated from North Carolina State University with Ph.D. degree, gained postdoc training from Duke University, and worked as an Assistant Professor from Boston University, a Principal Statistician in AstraZeneca – MedImmune and the Statistical Advisor for statistical works of three new drug development in CSRA – Dynport Vaccine Company. She is expertise in statistics in genomics, proteomics, drug development and clinical studies, especially in the development of novel machine learning methods for complex medical issues. She participated in the national-wide multi-center studies such as the Framingham Heart Study and the CHARGE Sequencing. She led the second stage drug component improvement of the lung cancer drug Imfinzi in Astrazeneca – MedImmune, and the development and management of four vaccines including rF1V, rBV A/B, huBChE and FluMist. She has published near 30 papers, with most as the major author in the top journals in the field of statistics and biomedicine. She has also won multiple research and leadership awards, and presented more than 60 times in national/international meetings, universities and pharmaceutical companies.