FINAL AGENDA

The 6th Meeting
MicroArray Quality Control (MAQC) Project

MAQC-II
Development and Validation of Predictive Signatures and Classifiers

Tuesday, November 28, 2006, 3:00 pm – 5:00 pm ET
at
Washington Marriott Hotel
1221 22nd Street NW
Washington, DC 20037-1294
+1-800-393-3053, +1-202-872-1500

Wednesday, November 29, 2006, 9:00 am – 4:00 pm ET
at
Room 2031, Central Shared Use Building
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903-0002

MAQC Phase II participants are encouraged to attend the FDA/DIA/PhRMA/BIO co-sponsored workshop on "*Best Practices and Development of Standards for the Submission of Genomic Data to the FDA*", November 27-28, 2006, Washington Marriott Hotel (http://www.diahome.org/product/12225/06036.pdf). Registration is required.

http://edkb.fda.gov/MAQC/

The 6th MAQC Project Meeting

DAY ONE, Tuesday, November 28, 2006, 3:00 pm – 5:00 pm ET
Washington Marriott Hotel, 1221 22nd Street NW, Washington, DC 20037-1294.
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Chair: **Yvonne Dragan** (NCTR/FDA)

MAQC-II Progress Report	3:00 pm	Chair's remarks	Yvonne Dragan
	3:05 pm	MAQC: From Phase I to Phase II	Leming Shi (NCTR/FDA)
	3:25 pm	Clinical Working Group	Uwe Scherf (CDRH/FDA)
	3:40 pm	Toxicogenomics Working Group	Federico Goodsaid (CDER/FDA)
	3:55 pm	MAQC Titration Working Group	Rich Shippy (GE Healthcare)
	4:10 pm	Gene expression profiling and breast cancer: state-of-the-art	Fraser Symmans (MD Anderson Cancer Center)
	4:30 pm	Characteristics of toxicogenomic biomarkers: the Iconix experiences	Kurt Jarnagin (Iconix)
	4:50 pm	Open discussion	All
	5:00 pm	Adjourn	

DAY TWO, Wednesday, November 29, 2006, 9:00 am – 4:00 pm ET
Room 2031, Central Shared Use Building, US FDA, 10903 New Hampshire Avenue, Silver Spring, MD 20903-0002.

Co-chairs: **Wendell Jones** (Expression Analysis) and **Weida Tong** (NCTR/FDA)

Clinical Data Sets	9:00 am	Criteria for the selection of clinical data sets	Wendell Jones
	9:10 am	Breast cancer	Fraser Symmans
	9:40 am	Multiple myeloma	John Shaughnessy (UAMS)
	10:00 am	Leukemia	Shujian Wu (BMS)
	10:20 am	Neuroblastoma	Andre Oberthür (Univ. Cologne)
	10:40 am	Coffee break	

Co-chairs: **Richard Simon** (NCI/NIH) and **Gregory Campbell** (CDRH/FDA)

Criteria for Performance Evaluation of Classifiers	11:00 am	Development and evaluation of predictive classifiers	Richard Simon
	11:10 am	Regulatory Biostatistics Working Group	Gregory Campbell
	11:20 am	Statistical goals of MAQC-II	Gene Pennello (CDRH/FDA)
	11:30 am	Glossary for classifiers and their evaluation	Tim Davison (Asuragen)
	11:40 am	**Open discussion** 1. Prediction accuracy, sensitivity, and specificity 2. Robustness of signatures 3. Mechanistic relevance 4. Within a single data set 5. Across multiple data sets 6. Prospective data sets	*Wendell to take notes*
	12:30 pm	Lunch (on your own)	

Co-chairs: **Federico Goodsaid** (CDER/FDA) and **David Dix** (EPA)			
Toxicogenomics Data Sets	1:30 pm	Iconix CIIT EPA EBI NIEHS ……	Donald Halbert Rusty Thomas David Dix
Titration Data Sets	2:30 pm	MAQC Main Study data set (ABCD) Titration Pilot data set (13 titration mixtures) New mixtures?	Rick Jensen
Logistics	2:45 pm	**Prospective studies** Samples Arrays Timeline	Fraser Symmans John Shaughnessy Donald Halbert Array manufacturers ……
	3:15 pm	Confidentiality Intellectual properties	All
	3:40 pm	**Action items/Timelines** Biweekly conference call for each WG Monthly conference call for the entire MAQC Submission of raw data to NCTR by 12/15/06 Array QC team Data distribution and CDA by 1/31/07 Initial results discussed at FDA Science Forum, April'07	All
	3:55 pm	Closing remarks	Leming Shi
	4:00 pm	Adjourn	

Background: The MAQC Phase I (MAQC-I) has demonstrated the technical reliability of microarray technology in detecting differential gene expression. However, questions remain regarding the reliability of the technology in clinical applications such as disease diagnostics or prognostics, and for tailored treatment based on gene expression profiles. To investigate the capabilities and limitations of microarray technology in such real-life applications, the MAQC Phase II (MAQC-II) has been launched to address technical and scientific issues involved in the development and validation of predictive signatures and classifiers. Multiple data sets will be collected and distributed to participating organizations for independent analyses with available algorithms. The resulting classifiers will be evaluated at three different levels: within a single data set via cross-validation, validation across multiple data sets from studies with the same study objectives, and prospective validation with additional data from new samples. It is anticipated that the MAQC project, through the community's active participation, will help develop "best practices" for the generation, analysis, and application of microarray data in the discovery, development, and review of FDA-regulated products. For more information about the MAQC project, please contact Leming.Shi@fda.hhs.gov and visit http://edkb.fda.gov/MAQC/.