AGENDA

The MicroArray Quality Control (MAQC) Project:

An FDA-Led Effort Toward Predictive and Personalized Medicine

The 9th MAQC Project Meeting

Best Practices for Developing and Validating Microarray-based Predictive Models

Thursday-Friday
September 18–19, 2008
9:00 am – 6:00 pm Eastern Daylight Time

at
US Food and Drug Administration
Building 51, Room 6200
10903 New Hampshire Avenue
Silver Spring, MD 20903, USA
http://www.fda.gov/oc/whiteoak/

Meeting Objectives:

1. Report on the selection of MAQC-II "candidate" models
2. Analysis of prediction results on the validation sets
3. Progress report on the preparation of manuscripts
4. Timeline

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

http://www.nature.com/nbt/focus/maqc/

Participants should consider information exchanged during the MAQC meeting as confidential.

Thursday, September 18, 2008 (Day One)

8:00 am	Registration (participants should arrive at the FDA campus no later than 8:30 am in order to be cleared at the security checkpoint in time)	
Session I-A: MAQC-II Overview and Selection of "Candidate" Models Chair: **Federico Goodsaid** (CDER/FDA)		
9:00 am	Welcoming remarks	Federico Goodsaid
9:10 am	Overview of submissions of models and prediction results; Review of meeting agenda	Leming Shi (NCTR)
9:30 am	Review of Data Analysis Protocols (DAPs) and ranking of candidate models by the RBWG	Greg Campbell (CDRH)
9:50 am	Selection of MAQC-II candidate models by the Steering Committee	Wendell Jones (EA) Russ Wolfinger (SAS)
10:10 am	Comments from Data Analysis Teams (DATs)	DAT Leaders
10:40 am	Coffee Break	
Session I-B: Prediction Results from the Validation Data Sets Chair: **Greg Campbell** (CDRH/FDA)		
11:00 am	Important observations from Data Analysis Teams regarding the prediction of validation sets	Volunteering DATs are welcome.
12:00 pm	Rules on the calculation of prediction performance metrics for all models	Wendell Jones (Expression Analysis)
12:15 pm	Prediction performance of MAQC-II candidate models; Release of prediction performance metrics and individual sample prediction results for all models	Leming Shi (NCTR)
12:30 pm	Lunch (on your own)	
Session I-C: Manuscripts (1) – Modeling Factors and Microarray Reality Check Chair: **Lakshmi Vishnuvajjala** (CDRH/FDA)		
2:00 pm	1. MAQC-II "main paper": Reaching consensus on the "best practices" in developing and validating microarray-based predictive models for personalized medicine	Leming Shi (NCTR)
2:15 pm	2. Minimizing the impact of batch effects in microarray data on the performance of predictive models	John Zhang (SAI)

	3. Microarray normalization methods and prediction performance	*(Ken Hess, MDACC, absent)*
2:30 pm	4. Evaluation of cross-platform consistency and transferability of microarray-based molecular signatures	Weida Tong (NCTR)
2:45 pm	5. Cross-tissue predictability of microarray genomic markers	Pierre Bushel (NIEHS, via WebEx)
	6. Cross-generation consistency in the prediction of treatment outcomes of multiple myeloma patients using different generations of the Affymetrix GeneChip microarrays (U95Av2, U133A, and U133Plus2.0)	*Yiming Zhou (UAMS, absent)*
3:00 pm	7. Comparison of one-color and two-color microarray platforms for the classification of neuroblastoma based on gene expression profiles	Russ Wolfinger (SAS) Benedikt Brors (DKFZ)
3:15 pm	8. Microarray data quality and its impact on classifier performance: a simulation of the impact of common technical defects in microarray data on classification and prediction results	Wendell Jones (Expression Analysis)
3:30 pm	9. Evaluation of technical robustness of genotyping in genome-wide association studies	Huixiao Hong (NCTR)
3:45 pm	Coffee Break	
Session I-D: Manuscripts (2) – Functional Analysis, SOP, and Multiplicity Chair: **Jim Fuscoe** (NCTR/FDA)		
4:10 pm	10. Biomarker discovery from dynamic biological networks 11. Biomarker discovery using meta-analysis	Tieliu Shi (CAS)
4:30 pm	12. Meta-analysis of gene features to compare predictive models	Youping Deng (USM, WebEx)
4:45 pm	13. Comprehensive functional analysis of data sets and gene signatures used in the MACQ-II project	Yuri Nikolsky (GeneGo)
5:00 pm	14. Principles of classifier development: SOP 15. Multiplicity and selection of candidate models	Greg Campbell (CDRH)
5:20 pm	16. Analysis of external validation results with adjustment for multiplicity in the MAQC-II	Gene Pennello (CDRH)
5:35 pm	Discussion	All
5:55 pm	Summary of Day One	Leming Shi (NCTR)
6:00 pm	Adjourn Day One	

Friday, September 19, 2008 (Day Two)

Session II-A: Manuscripts (3) – Uncertainty, Clinical Utility, and Consensus Chair: **Weida Tong** (NCTR/FDA)		
9:00 am	17. Uncertainty estimation in the assessment of classification models with a finite data set	Weijie Chen (CDRH)
	18. Significance tests for comparing multiple results in the MAQC-II	*Xuegong Zhang (Tsinghua, absent)*
9:15 am	19. The clinical benefit of a microarray-based classifier	Samir Lababidi (CDRH)
	20. Predicting treatment outcomes of breast cancer patients with microarray gene expression profiles	*Lajos Pusztai (MDACC, absent)*
9:30 am	21. Good Clinical Practices (GCP) in using microarray gene expression data	Guy Tillinghast (Riverside)
9:45 am	22. MAQC, VXDS, and FDA guidance	Federico Goodsaid (CDER)
10:15 am	Discussion	
10:40 am	Coffee Break	
Session II-B: Manuscripts (4) – Timeline, Target Journal, and Discussion Chair: **Leming Shi** (NCTR/FDA)		
11:00 am	Timeline V1: October 6 (Full manuscript draft) V2: Nov. 3 (Revised) V3: Nov. 17 (Revised, ready for institutional clearance) V4: Dec. 1 (Revised, almost ready for peer review) VS: Dec. 8, 2008 (Submission for peer review) Target journal	Leming Shi
11:30 am	Discussion and action items	All
12:30 pm	Lunch (on your own)	
Session II-C: Manuscripts (5) – Parallel Discussions Co-Chairs: **Manuscript Team Leaders**		
1:30 pm	Analysis of prediction results	Russ Wolfinger (SAS) and more volunteers
1:30 pm	Parallel discussions by individual manuscript teams	
5:00 pm	Adjourn the Meeting	

Registration

This meeting is by invitation only. The following individuals are invited:

- Leaders of Data Analysis Teams (1 representative per team)
- Leaders of Manuscript Proposals (1 representative per proposal)
- Data Providers (1 representative per provider)
- Microarray manufacturers (1 representative per manufacturer)
- MAQC-II Steering Committee Members

If you plan to attend the meeting, please contact Leming Shi (Leming.Shi@fda.hhs.gov, +1-870-543-7387) as soon as possible so that a seat will be reserved for you.

Meeting Venue

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Contact: Federico Goodsaid
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Airports

Ronald Reagan Washington National Airport (DCA)
Washington Dulles International (IAD)
Baltimore/Washington International Thurgood Marshall (BWI)

Suggested Hotels

Crowne Plaza Hotel Washington DC-Silver Spring
8777 Georgia Avenue
Silver Spring, MD 20910
301-589-0800
http://www.cpdcsilverspring.com/?src=ppc_google_brand

Marriott Courtyard Silver Spring
8506 Fenton St.
Silver Spring, MD 20910
Telephone: 301-589-4899
http://www.silverspringdowntown.com/go/marriott-courtyard-silver-spring