



Project Meeting Agenda

Microarray QC Metrics and Thresholds: Calibrated RNA Samples, Reference Datasets, and Standard Datasets

Friday, February 11, 2005

Building 26 Room A103 (NCTR/ARL Videoconference Room)
National Center for Toxicological Research (NCTR), US FDA
3900 NCTR Road, Jefferson, Arkansas 72079

Videoconference:

8:30 am–12:00 pm CST
Conf. Room 2055, FDA White Oak Labs

Teleconference:

8:30 am–12:00 pm and 1:00–2:30 pm CST
Access #: 888-664-9854; Passcode: 13344

- 8:30 am Welcome remarks and overview of NCTR's research activities (**Dan Casciano**)
- 8:45 am Current genomics activities at
CDER (**Felix Frueh/Federico Goodsaid**)
CDRH (**Uwe Scherf**)
CBER (**Jing Han**)
- 9:00 am Presentation on the *Microarray QC Metrics/Thresholds* project (**Leming Shi**):
1. Project overview
 2. Selection of RNA samples
 3. Microarray experimental design
 4. "Gold standards" (qRT-PCR)
 5. QC metrics and thresholds
 6. Data sharing, management, and analysis
 7. Timetable
 8. Logistics, challenges, and benefits
 9. Expectations from the meeting
- 9:30 am Application of a Cross-platform RNA Standard for Assessing Microarray Data Comparability
Karol Thompson (FDA/CDER)
Jacques Retief (Affymetrix)
- 9:50 am Break
- 10:00 am Discussion session I (Chair: **Janet Warrington**)
(Participants: Please state your name/affiliation before you speak.)
RNA samples
Experimental design
"Gold standards" (qRT-PCR)
Data sharing, management, and analysis
QC metrics and thresholds
Task assignments
- 12:00 pm Lunch

- Tour of NCTR (Division of Systems Toxicology, **Yvonne Dragan**)
- 1:00 pm Discussion session II (Co-chairs: **David Dorris** and **Bob Setterquist**)
 Logistics
 Timetable
 Working groups
- 2:15 pm Meeting summary and action plan (**Leming Shi**)
- 2:30 pm **Close of meeting.**

List of Participants

At FDA/NCTR site (Building 26 Room A103):

1. Affymetrix: Janet Warrington VP (Emerging Markets and Molecular Diagnostics)
2. Affymetrix: Jacques Retief Manager (Data Analysis, Genomic Collaborations)
3. Ambion: David Dorris VP and GM (RNA Services)
4. Ambion: Bob Setterquist Group Leader (RNA Ampl. and Microarray Products)
5. Illumina: Shawn Baker Sr. Scientist (Expression Profiling)
6. ViaLogy: Bud Bromley VP (Business Development)
7. FDA/CBER: Jing Han Biologist (customized and Affymetrix microarrays)
8. FDA/CDER: Federico Goodsaid Sr. Scientist (PGx data submissions)
9. FDA/CDRH: Uwe Scherf Scientific Reviewer (microarrays)

FDA/NCTR:

10. Dan Casciano, Director
11. Yvonne Dragan Director, Division of Systems Toxicology
12. Fred Kadlubar Director, Division of Pharmacogenomics and Molecular Epidemiology
13. Jim Fuscoe Director, Center for Functional Genomics
14. Luke Ratnasinghe Director, Center for Structural Genomics
15. Weida Tong Director, Center for Toxicoinformatics
16. John Bowyer Biologist (filter arrays)
17. Varsha Desai Biologist (customized oligoarrays)
18. Lei Guo Biologist (Applied Biosystems platform, qRT-PCR)
19. Tao Han Biologist (customized oligoarrays)
20. Tucker Patterson Biologist (Agilent platform)
21. Jim Chen Statistician (microarrays)
22. Hong Fang Bioinformatician (microarrays)
23. Leming Shi Computational Chemist (data mining and microarray QC)

Via Videoconference (FDA's White Oaks Labs):

1. CDER: Felix Frueh Associate Director of Genomics, OCPB (PGx data submissions)
2. CDER: Karol Thompson, Team Leader, Molecular Toxicology/DAPR
3. CDER: Member from Dr. Karol Thompson's team
4. CDER: Member from Dr. Karol Thompson's team
5. CDRH: Maria Chan
6. CDRH: Joe Hackett
7. CDRH: Reena Philip
8. CDRH: Kate Simon
9. CDRH: Zivana Tezak

Via Teleconference:

| | | |
|----------------------------------|-------------------------------|------------------------------------|
| 1. Agilent: | Jim Collins | Microarrays |
| 2. Applied Biosystems: | Gary Schroth | Microarrays, qRT-PCR |
| 3. Applied Biosystems: | Lu Zhang | Microarrays, qRT-PCR |
| 4. Applied Biosystems: | Jack Zhai | Microarrays, qRT-PCR |
| 5. GE Healthcare: | Hrissi Samartzidou | Microarrays |
| 6. GE Healthcare: | Tim Sendera | Microarrays |
| 7. GE Healthcare: | Rich Shippy | Microarrays |
| 8. Stratagene: | Garvin Fisher | RNA samples, qRT-PCR |
| 9. Stratagene: | Natalia Novoradovskaya | RNA samples, qRT-PCR |
| 10. Full Moon: | Youxiang Wang | Microarray standardization |
| 11. Full Moon: | Yaping Zong | Microarray standardization |
| 12. Cedars-Sinai/UCLA: | Charles Wang | Microarrays, qRT-PCR |
| 13. Children's Hospital/Harvard: | Zoltan Szallasi | Microarrays, data comparison |
| 14. Children's Hospital/Harvard: | Roderick Jensen | Microarrays, qRT-PCR |
| 15. EPA: | Gregory Akerman | Regulatory review |
| 16. EPA: | David Dix | Genomic Effects / Reprod. Tox |
| 17. EPA: | J. Christopher Corton | Research Biologist |
| 18. EPA: | A few others | |
| 19. FDACVM: | Heather Harbottle | Customized platforms |
| 20. Naval Res. Lab: | Baochuan Lin | |
| 21. NIH/NCI: | Ernest Kawasaki (unavailable) | Microarrays |
| 22. NIST: | David Duerwer | Data comparison |
| 23. NIST: | Marc Salit (unavailable) | Standardization (ERCC & Metrology) |

Contact Information

FDA/NCTR/

1-800-638-3321

Leming Shi

870-543-7387 (O), 501-227-8590 (H), 501-258-3615 (M), leming.shi@fda.hhs.gov

Weida Tong

870-543-7142 (O), weida.tong@fda.hhs.gov

Lee Ann Branch (Secretary, Division of Systems Toxicology, NCTR)

870-543-7467 (O), 870-543-7686 fax, leeann.branch@fda.hhs.gov

Gaucht's Grill

3 Rahling Road, Little Rock, Arkansas 72223. 501-821-2818

(This is an informal restaurant so you can dress for your own comfort.)