

NCI – FDA Interagency Oncology Task Force (IOTF)
Science-Based Strategies to Optimize Cancer Drug
Development and Throughput

- q Interagency Agreement – FDA/NCI Partnership – May, 2003
- q Major subcommittees devoted to interventions development process, surrogate endpoints, clinical/development biomarkers; Imaging and imaging endpoints, advanced technologies (nanotechnologies), bioinformatics, prevention and training

Highlights of IOTF Progress to Date

- q Process Enhancement – *Exploratory INDs for Small Molecules/Biologics; New GMP Regulations for Experimental Agents.*
- q Markers of Clinical Benefit – *Imaging Endpoints; biochemical markers for drug development*
- q New Common Bioinformatics Platforms – Standards for *Clinical Trails Submissions; e-INDs; CRIX Project*
- q Advanced Technologies - *Critical Path Initiatives (Nanotechnology and Molecular Diagnostics)*
- q Training and Joint Appointments – *Training Programs for Ph.Ds and MDs*

PROCESS SUBCOMMITTEE

- q Draft guidance on Exploratory IND Studies (early Phase 1) issued (4/14/05) www.fda.gov/cder/guidance/6384dft.pdf. Comment period for draft guidance closed 7/13/05; NCI to provided broad input to FDA; 20 comments received

Docket No. 2005D-0122 Open for Public Review

- q Senior leadership team process in place – FDN/NCI liaisons for IND resolution issues
- q NCI will announce the roll out of the SLT pilot and website
- q Whitepapers in process for GMP and toxicology issues

Co-Chairs: **Michaele Christian (NCI); Janet Woodcock (FDA)**

IMAGING BIOMARKERS SUBCOMMITTEE

- q Mini-working group formed to focus on key imaging science issues for development of volumetric imaging for oncology (George Mills, FDA/Carl Jaffe, NCI)
- q NCI and FDA collaborated on a joint paper on FDG-PET. Manuscript final – published in Clinical Cancer Research (Gary Kelloff and Janet Woodcock)
- q Molecular Probes: A working group developed a whitepaper and subsequent manuscript
- q Public private partnership to develop imaging biomarkers in discussion (NCI-FDA-NIH Foundation- Private Sector)

Co-chairs: Janet Woodcock and George Mills (FDA); Gary Kelloff and Dan Sullivan (NCI)

BIOINFORMATICS SUBCOMMITTEE

- q Registry for Bioinformatics Research Data) Technical Pilot Web based clinical investigator and financial reporting system
- q Developing and incorporating standards for clinical trials data reporting (e.g. HL7 – adverse events reporting)
- q Work on eIND proceeding (electronic common Technical document in process)
- q Clinical trials reporting systems (in collaboration with Clinical Trials Working Group)

Co-Chairs (Ken Buetow (NCI) and Randy Levin (FDA))

NANOTECHNOLOGY SUBCOMMITTEE

- q Joint collaboration with NIST on Nanotechnology Characterization Laboratory (NCL) Protocols
- q March 25, 2005, FDA held “Use of Nanotechnology in New Drug Development” course attended by FDA reviewers, NCI staff and others
- q May 12, 2005, ASTM Standards meeting with NIST
- q Launch of FDA and NCI Nanotechnology websites (January 2005). FDA site: www.fda.gov/nanotechnology; NCI site: <http://nano.cancer.gov>
- q Development of FDA Publicly Available Data Base for nanoparticle characterization based on NCL protocols
- q Development of NCI/FDA/NIST MOU for collaborative research activities

Co-Chairs: Wendy Sanhai (FDA) and Greg Downing (NCI)

JOINT TRAINING SUBCOMMITTEE

- q Fellowship Programs widely advertised All Programs – extremely good response
- q Fellowship programs were presented at AACR and ASCO
- q Approximately 15 applications received in first round
- q Six fellows incoming to Oncology Product Research/Review Fellowship
- q Selection committee has approved one fellow in Cancer Prevention Fellowship Program
- q <http://iotftraining.nci.nih.gov>
- q (Raj Puri/Nancy Smith (FDA) and Jonathan Wiest (NCI) - CoChairs