Report of the Workshop to Review the NCI's Rapid Access to Intervention Development (RAID) Program November 2005

Presentation to the
National Cancer Advisory Board

September 7, 2006

John Mendelsohn, M.D.

Members of the RAID Program

Chair

John Mendelsohn, M.D.
UT M. D. Anderson
Cancer Center

Small-Molecules Panel

Philip Frost, M.D., Ph.D.
ImClone Systems, Incorporated

Stanton L. Gerson, M.D.
Case Western Reserve University

Michael R. Grever, M.D.
Ohio State University

William N. Hait, M.D., Ph.D. (Chair)
Cancer Institute of New Jersey

Dale E. Johnson, Pharm.,D., Ph.D., DABT
ddplatform LLC

Robert A. Kramer, Ph.D., (Reporter)
Bristol-Myers Squibb Company

Michael J. Morin, Ph.D.
Pfizer, Inc.

C. Patrick Reynolds, M.D., Ph.D.
Children's Hospital Los Angeles

Biologics Panel

James P. Allison, Ph.D.
Memorial Sloan-Kettering Cancer Center

Frank Calzone, Ph.D.
Amgen, Inc.

David Clark, Ph.D.
Centocor, Inc.

Kenneth G. Cornetta, M.D.
Indiana University

Elizabeth Jaffee, M.D.
Johns Hopkins School of Medicine

H. Kim Lyerly, M.D.
Duke University Medical Center

John W. Park, M.D., (Reporter)
University of California, San Francisco

Andrew Raubitschek, M.D.
City of Hope National Medical Center

Louis M. Weiner, M.D. (Chair)
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NCI Rapid Access to Intervention Development (RAID) Program

Charge to workshop, July 13, 2005:

- Invited by NCI to review goals, operations, track record
- Make recommendations

Format:

- Presentations by NCI leaders with Q and A
- Two breakout sessions and report back
- Teleconferences for follow up
- Draft report circulated for comment
- Final report, November 2, 2005

RAID Track Record

- Goal: remove barriers between laboratory discoveries and entry into clinical trials of new molecular entities.
- 7 years duration.
- 288 applications, 104 approvals, 58 projects completed or discontinued. Median duration of project 2-3 years.
- In 2004: 28 agents ready for clinical trials, 21 licensed, 24 INDs, few in clinic.
- 2/3 small molecules, 1/3 biologics.
- Expenditures averaged $12 million per year.

Major Issues

- Endpoint should be entry into Phase 0/I clinical trials.
- Review and oversight should involve continuity rather than ad hoc evaluation; yearly checks on progress; being tougher about requiring investigators to meet specific deadlines and milestones, or exit the project.
- NCI staff should be delegated greater authority over the process when investigators accept funds and then delay in meeting research targets, ignore recommendations, or lose interest.
- NCI drug development staff should have authority to oversee contractors selected by Frederick.

Major Issues (2)

- A two-tiered peer review system is proposed. The committee that provides the second (technical) review is charged with oversight, including a yearly follow-up of progress.
- NCI staff should exercise the authority to check the quality of compounds developed by investigators and contractors and to review data from their laboratories, in order to make decisions.
- Investigators should agree to accept (or formally address) advice and expertise provided by NCI, in a joint and collaborative effort to move their discoveries into the clinic. Note: they retain IP.

Comments (1)

- NCI staff who presented clearly understood the complexities of drug development. The participants felt that there are too few such individuals with the required experience and expertise to expeditiously move new drugs in the various NCI intramural and extramural programs into the clinic. Because of competition with big pharma and biotech companies, pay levels may have to be higher and authority may have to be increased.

Comments (2)

- The primary review process must be stringent in accessing the capability and commitment of the investigator and his/her institution to take a research discovery and perform the experiments required to move it into the clinic. Strict time lines should be set, with the opportunity for NCI experts to move into a strong mentoring position, or – if necessary – to take over the project (but not the IP).

Comments (3)

- This program has major challenges: coordinating a research project involving an academic researcher, NCI staff and resources, and contractors performing specific stages in the process.
- In summary, NCI should be friendly, supportive, but firm.