National Cancer Institute

Interactions with Industry

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Purpose of Presentation

- **To update the NCAB on interactions with industry relevant to the December, 2010, report of the ad hoc Working Group**
- **To describe the scope of current interactions with industry**
- **To describe limitations to interactions with industry and the potential to overcome some of them**

Thanks

- **Technology Transfer Center, NCI: Karen Maurey; Kathleen Carroll**
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- **Center for Scientific Strategic Initiatives: Jerry Lee, Henry Rodriguez, Piotr Grodzinski**
- **Office of the Director, NCI: Harold Varmus, John Czajkowski**

NCAB Report: NCI & Industry

- "Despite the importance of NCI and industry relations, barriers to this collaboration exist. **The relationship between intramural NCI investigators and the private sector is encumbered by tightly constraining conflict of interest regulations that limit collaboration and consulting and informal exchanges of information and collaboration**, in contrast to the relatively more flexible ties between industry and academic researchers. In some cases, these rules negatively impact the ability of NCI and NIH ICs to recruit and retain top level scientists from the private sector."
  - **December 2010 Report of NCAB Ad Hoc Working Group**

NCAB Report: NCI & Industry

- **“**Recommendation 1: **The Department of Health and Human Services should permit NIH scientists to engage in ethically conducted and fully transparent consulting and collaborative relationships with the private sector…as part of their official duties,** provided that the scientists receive prior review and approval from the Institute Director and from the NIH Office of the Director. Such interactions should be encouraged as an important avenue to progress cancer research.”
  - **December 2010 Report of NCAB Ad Hoc Working Group**

Purposes of Interactions

- **To promote public health by:**
  - **collaborating on joint research**
  - **conducting clinical trials**
  - **sharing research materials**
  - **sharing information**

Technology Transfer at NCI/NIH

- **NCI Technology Transfer Center**
  - **Transactional agreements (CDA, MTA, CTA, CRADA)**
  - Institute intellectual property issues, employee invention reports
- **NIH Office of Technology Transfer**
  - Patenting
  - Licensing
  - Policy

Most of these Interactions Depend on Formal Agreements

- **Common types of agreements:**
  - **Confidential Disclosure Agreement (CDA)**
  - **Material Transfer Agreement (MTA)**
  - **Clinical Trial Agreement (CTA)**
  - **Cooperative Research and Development Agreement (CRADA)**

Confidentiality Agreement (CDA)

- **Specifies how proprietary information will be treated**
- For NCI/NIH sharing confidential information with an outside party
- May be the first step to a collaboration
- No license options

Material Transfer Agreement (MTA)

- **Specifies transfer and use of research materials**
- Specifies recipient’s permitted uses
- No license options

Clinical Trial Agreement (CTA)

- **Specifies transfer and use of materials in research involving human subjects under a protocol**
- May be an investigational drug, biologic, or device
- Assigns responsibilities for addressing regulatory requirements, data rights, and publications
- No license options

Two Types of CRADAs

- **Regular CRADA**
  - A single stand-alone agreement
- **Umbrella CRADA**
  - Permits using an MTA to add a new collaborative project between NCI and the same company (much faster)

Number of Agreements with Industry (FY10)

- **CDAs: 281 new ones**
- **MTAs: 181 new ones**
- **CTAs: 19 new ones; 125 currently active**
- **CRADAs: 26 regular new ones, 17 added to existing umbrellas; 173 currently active**

Data compiled by Karen Maurey and Kathleen Carroll
Technology Transfer Center, NCI

Consulting with Industry

- **Permitted as part of regular duties**
  - **Compensation is not permitted**
  - **Not permitted to be exclusive**
  - **Usually done with a CDA in place**

Some Personal Experiences as an NCI Intramural Investigator

- HPV research activities:
  - CDAs with the two companies that manufacture the commercial HPV vaccines
  - CDAs with several other companies interested in HPV-related technology
  - Three-way CRADA to develop low-cost 2nd generation HPV vaccine
  - Reagents (MTA) and hands-on instruction for high throughput HPV neutralization assay
  - Fair access

Le Meilleurs des Mondes Possibles?
(The Best of All Possible Worlds?)

Leibnitz, 1710; Voltaire (Candide), 1759

No: Some limitations and possible improvements

CRADAs

- **Almost all are in the intramural Center for Cancer Research (CCR) or the extramural Division of Cancer Treatment and Diagnosis (DCTD)**
- **CRADA development requires multiple, time-consuming steps**
- **Efforts under way to shorten the time needed to put a CRADA in place**

Consulting with Industry

- **Not widely known that it is permitted**
- **Lack of honorarium and travel costs to NCI reduce this type of interaction**

Recruitment & Retention of Staff

- **Recruitment of senior staff sometimes poses challenges because a key activity of a possible recruit (or that of his/her immediate family) is determined to represent a conflict of interest**
- **It is theoretically possible to seek a waiver for such an activity, but this is usually a lengthy process**

Conclusions

- **Considerable interaction occurs between NCI staff and industry (collaborations, clinical trials, material transfers, substantive discussions)**
- **In some instances, establishing these interactions may take considerable time; efforts to abbreviate the process**
- **Conflict of interest regulations may affect some types of discussions with industry and may make it more difficult to recruit and retain some NCI staff**