Pfizer’s Centers for Therapeutic Innovation (CTI) for NIH Researchers

APRIL 2015
What We Will Cover

• What is CTI?

• Details on the NCATS-hosted Pfizer CTI seminar for NIH intramural researchers, April 13, 2015
Pharmaceutical R&D Is a High-Risk Process

10–15 years; $1.3 Billion

Drug Discovery
Preclinical
Clinical Trials
FDA Review
Scale-up to Mfg.
Postmarketing Surveillance

Pre-Discovery
~ 5,000 – 10,000 Compounds
3–6 Years
ND Submitted

Drug Discovery
250

Clinical Trials
Phase 1
20–100
6–7 Years
NDA Submitted
Number of Volunteers
Phase 2
100–500
Phase 3
1,000–5,000

FDA Review
0.5–2 Years
NDA Submitted

Scale-up to Mfg.

Postmarketing Surveillance
Indefinite

One FDA Approved Drug

Sources:
NIH’s Mission

...is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.
CTI Model for Biologics Collaboration

- Founded in 2010
- A pioneering R&D network initiated by pharma that uses a collaborative model to bring great ideas to fruition.
- CTI is an entrepreneurial group that partners with academic medical centers, foundations and now NIH to translate promising science into clinical candidates.

Pfizer’s work is based on authentic collaboration, reflected in shared decision making and aligned incentives.

Bringing together some of the world’s best resources — including NIH scientists, patients, academic researchers, foundations and Pfizer’s own scientists — to develop medicines faster and more efficiently.
Challenges to Pharmaceutical Industry and NIH

**Industry**
- Slow progression of pipeline
  - Increased cost of drug discovery and development
  - Decreased productivity
- Pressure from stakeholders, investors, physicians, legislators, regulators and patients

**NIH**
- Increased focus on translational medicine
- Funding pressures
- Investigators’ challenges: to translate discoveries to the clinic while maintaining “control”

**CTI**
New partnership seeking to deliver on the promise of innovative discoveries to treat diseases of high unmet medical need with differentiated new medicines
CTI Collaboration for NIH Scientists

The collaboration is designed to engage the NIH Intramural Research Program to create protein biologic therapeutic candidates directed at targets/pathways that lead to Phase 1 clinical trials and demonstrate proof-of-mechanism.
CTI Collaboration for NIH Scientists

• Through this collaboration:
  - NIH scientists can potentially advance research projects from the lab into the clinic using Pfizer resources to pursue scientific and, ultimately, clinical breakthroughs.
  - NIH has negotiated a master Cooperative Research and Development Agreement
    - Contact your Technology Transfer Office for more information
Focus on Monoclonal Antibodies

Antibody Modes of Action

- **Neutralizing Antagonist**
  - Antibodies that bind to a target and block an interaction

- **Agonist**
  - Antibodies that bind to a receptor and stimulate a downstream process

- **Effector Function (Cell Killing Mechanisms)**
  - **ADDC**: Antibody-Dependent Cell-Mediated Cytotoxicity
    - Recruits macrophages, monocytes or NK cells
  - **CDC**: Complement-Dependent Cytotoxicity
    - Recruits complement serum proteins
Project Proposals, Selection & Execution

Call for Proposals

Stage I:
Pre-Proposal Submission
Non-Confidential Review

Stage II:
Full Proposal Submission
Confidential Review

Stage III:
Work Plan and Budget
# Joint Steering Committee

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<th><strong>Co-Chairs</strong></th>
<th>NIH</th>
<th>Pfizer</th>
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<tr>
<td>Anton Simeonov, Ph.D.</td>
<td>Acting Scientific Director, NCATS</td>
<td>Anthony J. Coyle, Ph.D.</td>
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<th><strong>JSC Members</strong></th>
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<th>Pfizer</th>
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<tr>
<td>Raffit Hassan, M.D.</td>
<td>Co-Chief, Thoracic and Gastrointestinal Oncology Branch, Center for Cancer Research, NCI</td>
<td>Santiago Arroyo, M.D.</td>
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<td>John J. O’Shea, M.D.</td>
<td>Scientific Director, NIAMS</td>
<td>Will Somers, Ph.D.</td>
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<td>Kathryn C. Zoon, Ph.D.</td>
<td>Director of Intramural Research, NIAID</td>
<td>Charlotte Allerton, M.Phil.</td>
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<th>Pfizer</th>
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<td>Lili Portilla, M.P.A.</td>
<td>Director of Strategic Alliances, NCATS</td>
<td>Samantha O’Connor, M.B.A.</td>
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Seminar Details

Who: NIH and Pfizer CTI representatives

What: Learn more about how to collaborate with Pfizer’s CTI

When: April 13, 2015, 2-5 p.m.
      (Also April 14, 2015, one-on-one meetings by appointment)

Where: Lister Hill Auditorium, Building 38A, NIH

Why: To deliver on the promise of innovative discoveries to treat diseases of high unmet medical needs with differentiated new medicines

For more information and to register, e-mail NIH-CTIPfizer@mail.nih.gov.
For More Information

Visit the NCATS Web page about the NIH-Pfizer CTI collaboration:

www.ncats.nih.gov/cti