Academia/Government Taskforce Perspective: How to Enhance Cooperation Between Agencies and Academia

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Disclosures

•Compensated consultant: Lantheus, AstraZeneca, Amgen, Daiichi, Pfizer, Convergent, ITM Isotope Technologies, Clarity Pharmaceuticals, Blue Earth Diagnostics, Point Biopharma, Telix, Progenics, Z-Alpha

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Recognition of increasingly vexing issues in the cancer landscape about which there is little disagreement

Routine care

- Immense financial burden for cancer care
- drugs, lost wages, travel costs, dependent care
- Variable access to expertise
- Personnel shortages

→

- Individual financial burden to patients
- Social financial toxicity
- Inequitable access to care
- Compromised quality of care

Trials

- Overly complex designs
- Unnecessary data collection
- Poorly utilized biospecimens
- Long times to activation
- Restrictive eligibility criteria
- Late endpoints (e.g., OS)

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- Delays in drug approval
- Delays in biomarker qualification
- Increased trial expense/staff
- Inequitable access to trials

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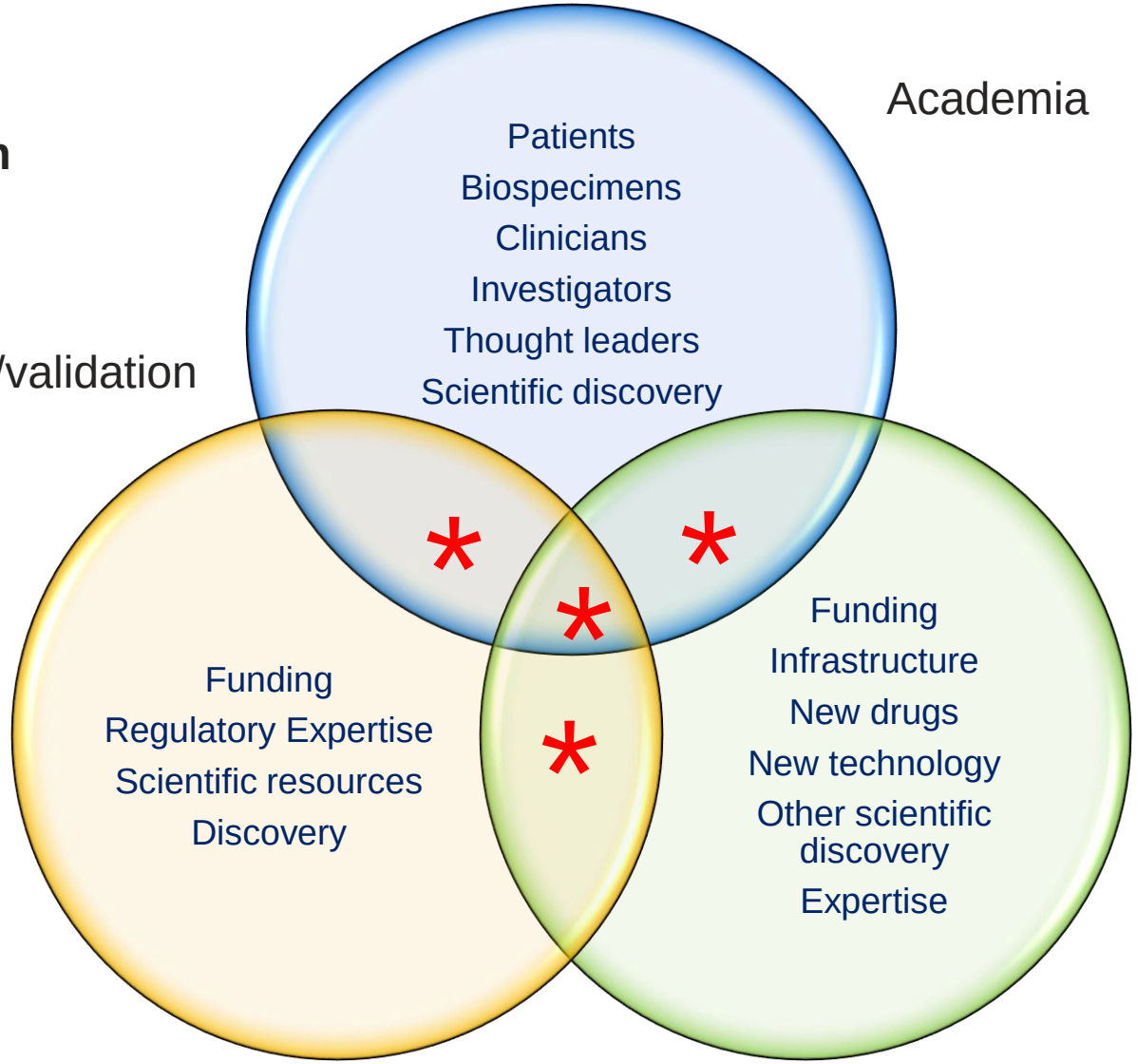
Multiple areas of coincident self-interest

* **Opportunities for gain**
  Scientific discovery
  Drug development
  Regulatory recognition
  Biomarker qualification/validation
  Improving outcomes



* **Opportunities for conflict**
  Control of process
  Control of data
  Ownership of IP
  Share of revenue

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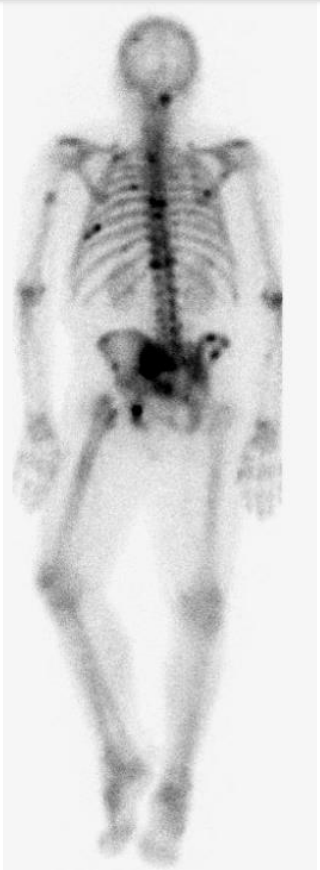
Case study: FDA, academics, and industry recognize a dilemma in prostate cancer

Non-measurable disease/late OS



Academic/FDA/Industry trial design criteria

Design and End Points of Clinical Trials for Patients With Progressive Prostate Cancer and Castrate Levels of Testosterone: Recommendations of the Prostate Cancer Clinical Trials Working Group

Howard I. Scher, Susan Halabi, Ian Tannock, Michael Morris, Cora N. Sternberg, Michael A. Carducci, Mario A. Eisenberger, Celestia Higano, Glenn J. Bubley, Robert Dreicer, Daniel Petrylak, Philip Kantoff, Ethan Basch, William Kevin Kelly, William D. Figg, Eric J. Small, Tomasz M. Beer, George Wilding, Alison Martin, and Maha Hussain

Trial Design and Objectives for Castration-Resistant Prostate Cancer: Updated Recommendations From the Prostate Cancer Clinical Trials Working Group 3

Howard I. Scher, Michael J. Morris, Walter M. Stadler, Celestia Higano, Ethan Basch, Karim Fizazi, Emmanuel S. Antonarakis, Tomasz M. Beer, Michael A. Carducci, Kim N. Chi, Paul G. Corn, Johann S. de Bono, Robert Dreicer, Daniel J. George, Elisabeth I. Heath, Maha Hussain, Wm. Kevin Kelly, Glenn Liu, Christopher Logothetis, David Nanus, Mark N. Stein, Dana E. Rathkopf, Susan F. Slovin, Charles J. Ryan, Oliver Sartor, Eric J. Small, Matthew Raymond Smith, Cora N. Sternberg, Mary-Ellen Taplin, George Wilding, Peter S. Nelson, Lawrence H. Schwartz, Susan Halabi, Philip W. Kantoff, and Andrew J. Armstrong

Academic/FDA/Industry trial design and data: Registration trials for abiraterone/enzalutamide

Association of rPFS and OS: Optimal as on-treatment rPFS

	# rPFS events	Median rPFS (mo's)	# Deaths	Median OS (mo's)	τ
A031201 rPFS (PCWG3)	864	22.5	711	33.4	0.70 (CI: 0.67, 0.72)
Cou-302[1] *(abi arm)*	271	16.5	186	27.2	0.63 (0.56-0.70)
PREVAIL[2] *(enza arm)*	387	19.7	241	32.4 (est)	0.72 (0.68-0.77)

Note:
A win-win for all stakeholders: academics, industry, FDA, and patients
No IP (although not without attempts to do so)
No revenue stream
No commercialized product

Scher, et al., J Clin Oncol 26:1148-1159; J Clin Oncol 34:1402-1418
Morris et. al J Clin Oncol, 2015; 33:1356-1363
Rathkopf et. al., JAMA Oncol, 2018;4(5):694-701

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How do we maximize the sweet spots in a systematic way that moves beyond one-off successes?

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Challenges to systematic changes to existing paradigms of academic/gov't partnerships

Academic:

- "Winners" vs "Losers" psychology
  - Enhanced in an underfunded environment
  - Suspicion that innovation and efficiency is code for other agendas

Government:

- Innovative mechanisms may be poorly served by existing infrastructure, staffing, and processes
- Existing mission/role is defined by regulation or legislation

Industry

- Risk aversion due to:
  - Threats to revenue
  - Threats to data secrecy
  - Threats to IP
  - Threats to corporate SOP's

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NCI Strategic Vision for Clinical Trials: 2030 and Beyond

Develop **flexible**, **faster**, **simpler**, **less expensive**, **high-impact** clinical trials that seamlessly integrate with clinical practice

- Streamline processes for trial design and execution
- Focus on essential endpoints
- Decrease regulatory hurdles and broaden trial access
- Increase efficiency of data collection

CTAC Strategic Planning Working Group 2020 report:
https://deainfo.nci.nih.gov/advisory/ctac/1120/SPWGreport.pdf

NCI Clinical Trials Innovation Unit: A means of testing innovative collaborations, interventions, biomarkers, procedures, designs, and problem-solving

Small, nimble, and collaborative

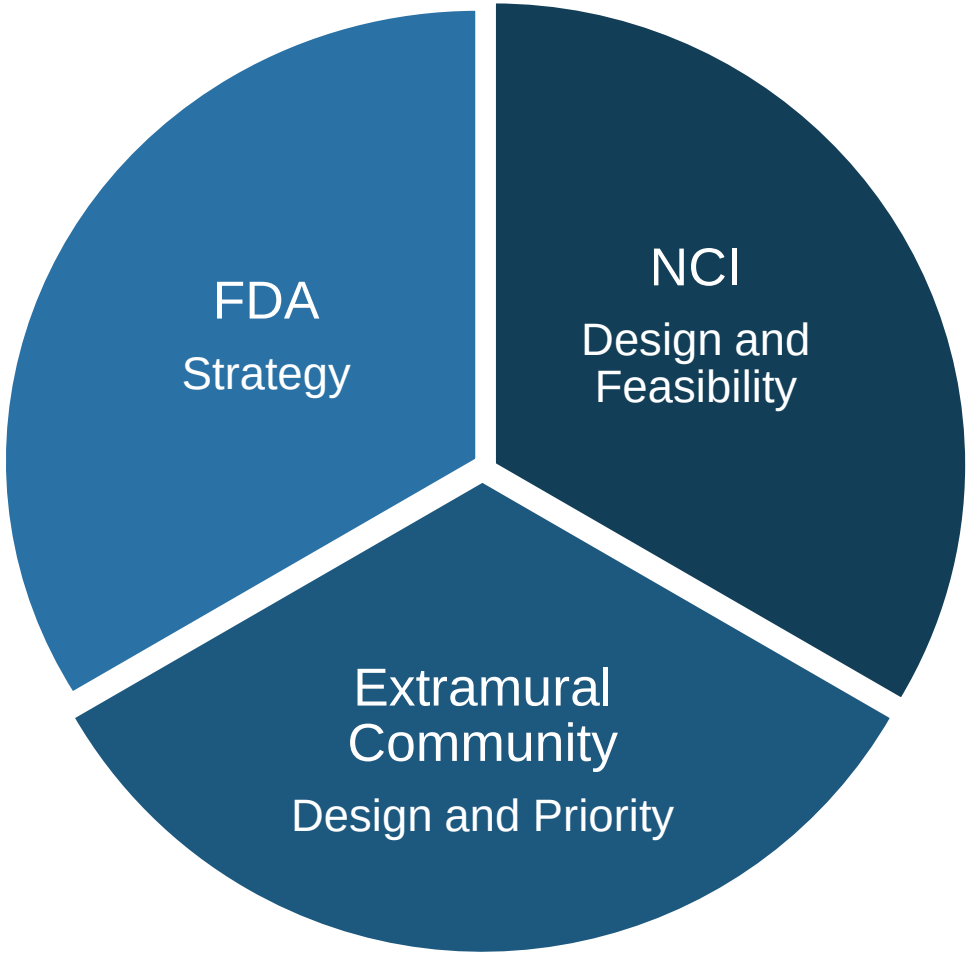
Co-Directors/Facilitators: Michael Morris, Sheila Prindiville

CTIU: Where innovation and collaboration can be tested without breaking things

Reservoirs of Ideas

- NCTN
- NCORP
- Industry
- Foundations

Multidisciplinary Expertise



Pilot Phase Submission Process: Focused proposals with rapid turnaround

1-2 page submission by investigator
(up to 4 per group)

Rapid vetting by CTIU of ideas

Evaluation of proposals selected to advance on the basis of innovation

Additional *ad hoc* external disease experts and advocates

Enhancing government/academic collaboration

- Recognition of the complementary assets, gains, and risks of each stakeholder
- Recognition of where the interests of each do *not* overlap
- CTIU is designed as a new collaborative space in which a multiagency group can test how to systematically change:
  - How trials are performed
  - How collaborations are made
  - How processes are implemented
  - How problems are solved