Treatment: Accelerating Cancer Research

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Treatment Advances Since 2011

• Immunotherapy
• No longer treat cancer simply by type or stage
• New drug approvals
Initiatives to Accelerate Cancer Research

• Funding
• Accrual
• Overhaul of System
• Big Data
• Efficiencies in Trial Conduct
FACT SHEET: Investing in the National Cancer Moonshot

During his 2016 State of the Union Address, President Obama called on Vice President Biden to lead a new, national “Moonshot” initiative to eliminate cancer as we know it. Today, the White House is announcing a new $1 billion initiative to jumpstart this work.

Too many American families know all too well the devastation cancer can bring. More than 1.6 million new cases of cancer will be diagnosed and cancer will kill an estimated 600,000 Americans in 2016. Cancer doesn’t discriminate - it strikes young and old, family and friends, neighbors and co-workers. As the President said, we must harness the spirit of American innovation to identify new ways to prevent, diagnose, and treat cancer.
NCI Funding: Actual vs Inflation Adjusted

Accounting for Inflation, NCI's budget has decreased by more than $1.1 billion (24.7 percent) since FY 2003.
Funding

- Provider: per-case reimbursement
- Patient: Insurance coverage

An investment in knowledge pays the best interest.
– Ben Franklin
Clinical Trial Accrual

National Cancer Institute. NCIs Clinical Trials Programs and Initiatives, 2014.

- Approximately 3-5\% of adult cancer patients participate in clinical trials
- 40\% of all NCI-sponsored trials suffer accrual failure

Factors Predicting Low Accrual in Cancer Clinical Trials

- Higher Competition per 10,000 eligible patients per year
- Conditions with low annual incidence
- Larger enrollment fraction of eligible patient population
- Nonmetastatic setting
- Treatment related
  - Multimodality therapy
  - Surgery
  - Radiation therapy

Improving Accrual: Eligibility Criteria

- Restrictive criteria impact accrual
  - Increase regulatory burden?
- Impact of number of eligibility criteria on accrual
- Development of eligibility criteria that allow broadest population possible
- NCI Network Accrual Core Team (ACT)

Accrual to Precision Medicine Trials

- Low clinical trial accrual rate is universal in genomic screening studies
- Community based cancer centers need to be integrated in precision medicine trials

Overhaul of the Clinical Trial System

- Modernizing measurement of tumor response to therapy
- Capturing Adverse Events, PRO-CTCAE
- Expansion Cohorts in Phase 1 Trials

Big Data

- Project Data Sphere
- CancerLinQ
- Project GENIE
- 21st Century Cures Act

Efficiencies in Trials and Reporting

• Opening a phase III cooperative group trial requires a median time of 2.5 years from concept review to opening
• Activation time ranged from 435 to 1,604 days
• At centers, cooperative group trials are more likely to have zero accruals than non-group trials
• 40% of all NCI-sponsored trials suffer accrual failure, in part due to delayed study activation
• Publication of negative results

Publicly Funded Clinical Trial System Overhaul

• Consolidated the 11 cooperative groups to 5 network operation groups
  – National Clinical Trials Network (NCTN)

• Greater collaboration among stakeholders in cancer research

Opportunities for Collaboration
The Big Ten Cancer Research Consortium

Teaming up to fight cancer
Member Institutions

- University of Illinois
- Indiana University
- University of Iowa
- University of Michigan
- Michigan State University
- University of Minnesota
- University of Nebraska
- Northwestern University
- Penn State University
- Purdue University
- Rutgers, The State University of New Jersey
- University of Wisconsin
Mission

The Big Ten cancer centers have united to transform the conduct of cancer research through collaborative, hypothesis-driven, highly translational oncology trials that leverage the scientific and clinical expertise of Big Ten universities. The Big Ten Cancer Research Consortium creates a unique team-research culture to drive science rapidly from ideas to treatment-changing paradigms. Within this innovative environment, today’s research leaders collaborate with and mentor the research leaders of tomorrow with the unified goal of improving the lives of all patients with cancer.
A New Era in Cancer Care

Clinical trial focus will be on
• Translational research, Phase II or earlier
• targeted agents
• genomics-based individualized therapy

The nature of the current clinical trial environment and personalized medicine clinical trials necessitates an ability to open trials quickly and efficiently.
BTCRC Resources for Clinical Trials

- Clinical Trial Development and Approval
- Budgets
- Contracting
- Biorepository
- IRB Process
BTCRC Structure

Steering Committee

Executive Officer

- GU CTWG Oct 2013
- GI CTWG Feb 2014
- Thoracic CTWG Jan 2014
- Breast CTWG May 2014
- GYN CTWG Nov 2014
- Heme CTWGs (leukemia, myeloma, lymphoma) Dec 2014
- Melanoma CTWG Dec 2014
- Genomic/Phase I CTWG

CTWG: Clinical Trial Working Group
Progress to Date

• June 2013  BTCRC kickoff held at ASCO
• Oct 2013  First Clinical Trial Working Group
• Nov 2013  Meeting of IRB representatives
• First trial opened in March 2015
  – Time from LOI approval by Clinical Trial Working Group to IRB Approval at lead site: 138 Days
• Three trials (hepatic, esophageal, breast) to open in the next few weeks
• More than 20 concepts in development across multiple tumor types
BTCRC-GU14-003 Cumulative Accrual

Cumulative Accrual vs Months

- Blue bars: Cumulative Accrual
- Orange line: Planned Accrual


Cumulative Accrual:
- Apr15: 0
- May15: 5
- Jun15: 10
- Jul15: 15
- Aug15: 20
- Sep15: 25
- Oct15: 30
- Nov15: 35
- Dec15: 40
- Jan16: 45
- Feb16: 50
- Mar16: 55
- Apr16: 60
- May16: 65
- Jun16: 70
- Jul16: 75
- Aug16: 80
- Sep16: 85
- Oct16: 90
- Nov16: 95
- Dec16: 100
- Jan17: 105
- Feb17: 110
- Mar17: 115

Planned Accrual:
- Apr15: 0
- May15: 5
- Jun15: 10
- Jul15: 15
- Aug15: 20
- Sep15: 25
- Oct15: 30
- Nov15: 35
- Dec15: 40
- Jan16: 45
- Feb16: 50
- Mar16: 55
- Apr16: 60
- May16: 65
- Jun16: 70
- Jul16: 75
- Aug16: 80
- Sep16: 85
- Oct16: 90
- Nov16: 95
- Dec16: 100
- Jan17: 105
- Feb17: 110
- Mar17: 115
BTCRC: Accelerating Cancer Research

• Leverages respective strengths of academic cancer centers to develop multidisciplinary translational research protocols to enhance the quality and impact of trials.

• Provides access to a large patient population to facilitate the accrual

• Decreased time to publication through multicenter accrual

• Attractive for funding sponsors due to streamlined operations
Keys to Accelerating Cancer Research

• Funding
• Increase in trial accrual
• Remove restrictive trial phases
• Addressing patient privacy through Big Data
• More nimble clinical trial approval process
“If we knew what it was we were doing, it would not be called research, would it?”
– Albert Einstein