

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
NATIONAL CANCER INSTITUTE**

**MINUTES OF THE 58th DIRECTOR'S CONSUMER LIAISON GROUP MEETING
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Members Present

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Ms. Andrea Ferris	McMurry-Heath	
Ms. Joya Delgado Harris	Dr. Deborah Morosini	

Speakers

Dr. James Abbruzzese, The University of Texas MD Anderson Cancer Center
Dr. Giuseppe Giaccone, National Cancer Institute
Dr. Javed Khan, National Cancer Institute
Dr. Shivaani Kummar, National Cancer Institute
Dr. Lee Helman, National Cancer Institute
Dr. Lisa McShane, National Cancer Institute
Dr. Barbara Conley, National Cancer Institute
Dr. Donald Berry, The University of Texas MD Anderson Cancer Center
Dr. Jane Perlmutter, Gemini Group
Dr. Helen Chen, National Cancer Institute
Dr. Patricia Keegan, US Food and Drug Administration
Dr. Barbara Wold, National Cancer Institute

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The Challenge of Translating the Science of Oncology to Patient Care

Dr. James Abbruzzese

- Advances in basic science leads us to many therapeutic opportunities
- Phase II Trials are a critical juncture in the development of successful therapies
 - Provide a go/no go decision
 - High degree of activity in a certain population can lead to early approval
 - Results must be interpreted carefully
- Novel clinical designs used to increase success rate
 - Phase 0 trials
 - Randomized discontinuation trials
 - Adaptive trial designs
- Current designs are fully capable of identifying highly active agents when the science dictates
- Highest priority should be basic science with the potential for high clinical impact

Dialogue with the DCLG

- What kind of inferences should people draw from failures in phase III trials? The results of a poorly designed trial?
 - You can make an argument that companies are lenient with which compounds they allow to go into phase III
 - Look at the rigor with which the phase II trial was done and the size of the trial
 - In terms of safety – we will always have to accept that late toxic effects may be a problem that will not show up in early trials
- Do you see enrolling different tumor types in phase II trials?
 - I see a hybrid system, we will still look at disease site and mutation type
 - Vemurafenib success in melanoma and failure in colorectal cancer illustrates a problem with this approach
- What can the community do to help prevent failure?
 - Have healthy skepticism of phase II trial data
 - Continue to advocate for basic scientific discovery
 - The biomarker is the target, but we don't have enough information on what happens when mutations occur

Advances in Basic Science are Placing New Demands on the Clinical Trial Process

Dr. Giuseppe Giaccone, Dr. Javed Khan, Dr. Shivaani Kummar

Dr. Giaccone – [Molecular Profiling of Thoracic Malignancies](#)

- Thoracic tumor trial in his lab

- Ongoing trials in NSCLC, SCLC, thymic cancer
- Cost of sequencing technology is coming down rapidly
 - Matches the time required

Dr. Khan – [How Science Conducted in the Lab is Changing the Structure of Clinical Trials](#)

- mRNA diagnostic and prognostic biomarkers
 - Highly accurate biomarkers can be used in diagnosis of pediatric cancer
 - Barriers
 - Low interest from industry
 - Low awareness by clinicians
 - Predicting outcome of individual tumors may be possible
 - Barriers
 - Even with predicted outcomes, there's a lack of validated targets and drugs
 - mRNA expression signatures are fraught with inherent problems
- Next generation sequencing
 - There are efforts to do large-scale pediatric sequencing of pediatric cancers
- Using genomics to personalize therapy

Dr. Kummar – [Role of Phase 0 Trials in Anti-Cancer Drug Development](#)

- Where do we stand in oncology drug development?
 - Oncology drugs take longer than other classes and are less successful in gaining approval
- What do we need to develop effective new drugs?
 - Ways to measure drug levels and assess changes in target
 - These need to be developed prior to and incorporated into clinical trials
- FDA's Exploratory Investigational New Drug application
- Concept of Phase 0 trials
 - Increase chance of success in later phases of drug development
 - Expedites the drug development process
 - Eliminates poor drug candidates early in the process
- Developmental Therapeutics Clinic, NCI – our experience with the first phase 0 trial in oncology

Dialogue with the DCLG

- Are researchers looking for ethnicity in research?
 - The data is collected and will be examined in the future
- How often are trials like the ones done by Dr. Giaccone performed?
 - Not very broad as yet, but as the sequencing has become cheaper and faster, this will become much more available.
- Is the data collected now going to be valid in the future?
 - Some data is not reproducible, which is a barrier for use in patients

Cancer Research in the 21st Century

Dr. Lee Helman

- There is a shifting paradigm in cancer research and treatment
- Imaging is increasingly being used in early detection, diagnosis, and treatment
- The drive to make improvements is to understand this biological process called cancer
 - Putting more science into clinical trials
 - This call is coming from clinical researchers
- This is leading the drive to individualized medicine

Dialogue with the DCLG

- What is the role of external stakeholders?
 - Engage with IRBs and regulatory agencies
 - We can't keep doing business as usual
 - We need to balance performance with what is an acceptable risk
- Are the genetic mutations we're seeing in cancer existing in different diseases being studied at NIH?
 - Mutations accumulate over a lifetime
 - UV light, etc.
 - Some mutations are drivers in one site and silent in another
 - Children's cancer are catastrophic mutations
- How do we deal with ever smaller groups of patients with mutations where each mutation is a rare cancer?
 - If you have the right drug for the right patients, you don't need 3,000 patients
 - Crizotinib was ~80% effective in 100 patients

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Aspects of Novel and Traditional Clinical Trial Design

Dr. Lisa McShane

- Few therapies will help all cancer patients, but we expect big benefits in the targeted groups
- During clinical trials, when do we change the patient population from all comers to targeted groups?
 - It's a judgment call as to whether you have faith in the biology
- These biomarker-driven trials need ever larger sized trials to power the trial to have a significant conclusion
- Patient participation is crucial for the success of these trials, especially in trials with rare biomarkers
- Advocacy has a role in getting different pharmaceutical companies to work together and trial their drugs head to head

- It is important for community to push for good quality specimens and assess the tumors for biomarkers.

Dialogue with the DCLG

- In regard to specimens, it's not the patient population; there is an issue with the community oncologists not wanting to collect or analyzing.
 - It's also an IRB issue and pathologists often don't want to do it or don't have the time
 - The IRBs have to understand that the patients are willing to take risks associated with the collection of biomarkers
 - Some community cancer centers don't have the infrastructure to collect samples; it requires an investment of time and money
 - Patients should make sure that the powers that be know that they believe this is important
 - Even pharmaceutical companies have trouble collecting samples
- How valuable is whole genome sequencing for a statistician designing a trial?
 - There is a problem of consistency among labs
 - It's good for data mining, but data mining often results in many false positives
- How big an issue is variability in assays?
 - If the signal is strong enough, you can get beyond the noise (ex, ER, HER2)
 - What does this mean for the patient when there are contradictions?
 - Over 3,000 women per year are analyzed to be HER2- when they're actually HER2+
 - Could the weakness of trastuzumab be caused by faulty lab analysis?
- Where are we in retrospective analysis?
 - FDA taking a risk-based approach in allowing laboratory developed tests to be used without FDA approval. FDA is drafting guidance for this.

Co-development of Diagnostics and Therapeutics for Cancer

Dr. Barbara Conley

- Co-development of diagnostics and therapeutics; diagnostic is as important as the treatment
- Biomarkers are the ultimate in personalized medicine (can include biological, drug, or imaging biomarkers)
 - Successful development of biomarker studies is uncommon
- There are issues with various routes of testing and variation in testing of biomarkers
 - They do not occur in linear fashion or consistently across the board
 - CLIA: Lab certification not test certification
 - FDA approves if test measures what supposed to measure, not utility to patient
 - Investigational device exemption (IDE)

Dialogue with the DCLG

- What can NCI do to help with this space? FDA is still not focusing on clinical utility (FDA CDRH follows the law in this) in approvals. Could NCI pick up testing how helpful diagnostics are to patients?
 - The pharmaceutical industry is not against this testing; however, science is going faster than the ability to test but will get there eventually
 - The NCI DCTD has the Clinical Assay Development Program
 - Many things can change in an assay (machine setup, sample collection, programs used, etc)...there is a need to validate
- What other role might advocates have in this realm?
 - Education for patients, lawmakers, insurers, etc. around validation; should we be looking more toward assays that measure multiple items even if not FDA approved or cleared vs. approved/cleared test for one (ex: BRAF) because sample size is so small and may not have enough to run multiple individual tests
 - Investigators may not be interested in collecting additional samples (i.e., serum) because of increased costs. The community can have a role in larger and more varied samples being collected.
 - Address investigator/community oncologist reluctance to asking for consent and collecting
- IRBs are serving as a block, rather than assistance, to patients related to sample collection
 - Depends on invasiveness of the biopsy; patients should be allowed to make those decisions, clinicians may see as protecting patients from bad decisions
- Where are we in validating a piece of equipment vs. a test? Technology going toward sequencing whole genome. Could we just validate genome sequencer?
 - Under consideration at the FDA, but it is a big decision. There are concerns with software updates and mechanical issues. Cost of machines is an issue.
 - Cost of gene sequencing for individual tests (including multiplex) are becoming more expensive as more whole genome sequencing is occurring
 - Not enough time/experience with multiplexes to validate all portions

Adaptive Trial Design and Personalized Therapy Trials

Dr. Donald Berry, Dr. Jane Perlmutter

- Phase III trials in oncology are not frequently successful for various reasons
 - How to resolve high failure rate
 - Increased use of adaptive and Bayesian trials
 - Streamlining clinical trials
 - Biomarker development
- Adaptive trials have multi-stage designs and are fully specified at the beginning, but change during the period of the trial based on testing (changes are specified)
 - Increasingly gaining acceptance
 - Can lead to more rapid, cost-effective progress and identifying more effective treatments

- Major adaptive trials – BATTLE (lung cancer), I-SPY trials (breast cancer), MELTTT (melanoma), trial in colorectal cancer about to start
- [I-SPY 2 Trial](#)
 - Simultaneously validating biomarkers and assessing investigational agents (multiple)
 - Multiple funding sources/partnerships
 - Lessens time and number of participants required
 - Comparing drugs to standard of care, not to each other

Dialogue with the DCLG

- If a treatment is not effective, are patients re-randomized?
 - This is planned for I-SPY 3
- Questions around randomization/assignment
 - Patients are tested for multiple biomarkers and randomly assigned to drugs known/expected to affect those specific biomarkers; stratified based on past success rates of the drug (showing more success gets higher percentage of patients)
- What is I-SPY 3?
 - Imaging; what sequence should you treat patients; re-entering patients into trials; broadening from standard assays and biomarkers to target more specifically
- What is NCI doing to encourage the use of adaptive trials?
 - We didn't discuss barriers and challenges of adaptive trials and how NCI is addressing these
 - Cooperative groups not involved in adaptive trials
 - NCI providing some funding for I-SPY trials (Foundation for the National Institutes of Health); funding limited specifically for data analysis/statistics—how to conduct when have limited resources in this realm
 - IT infrastructure is big issue; previously used caBIG but cannot be done in the cooperative groups in the same way; the enthusiasm is there but the funding is not
- What about manpower?
 - We need additional manpower, but the work could also be done more efficiently
- Are you saying there is no manpower to do this within NCI infrastructure?
 - I was speaking about the cooperative groups
- Are adaptive trial applications being prioritized in any way in review?
 - Everything goes through peer review process; applicants have to justify that this (adaptive) is a better way to go in the specific instance
 - There is an educational initiative to educate reviewers at NCI, an effort to establish database of all clinical/biomarker trials to serve as a resource for evaluating adaptive designs; there is hype associated with adaptive designs, so there may be a subconscious advantage in application process
 - This ties in with all other topics about how clinical trials are changing, better trials vs. different trials, changing science, etc. We have to keep moving forward while using the current infrastructure and resources because we don't have ability to turn on a dime

- How do you expect the FDA to be in giving a pass-forward here? Past complete response of x?
 - We had a discussion of registration pathway several months ago; looking for big results—show effect on past complete response within subset of patients, would need that plus additional confirmation outside of I-SPY; this could lead to the possibility of accelerated approval; We have worked with Janet Woodcock at FDA
- What is the financial advantage of this type of trial vs. doing each element individually?
 - Adaptive trials benefit from a single control group; more patients are assigned to better performing therapies so they move through the process more quickly and eliminate poor performers more quickly (although this is controversial because you don't want to eliminate something useful); this lowers the size of phase III trials; there is savings from each, but no specific numbers available yet; however, it is attractive to for-profit companies because of these potential cost savings

From Target Discovery to Therapy – Clinical Development of Single or Combinations of Anticancer Drugs

Dr. Helen Chen

- Translation from biology to therapy
 - Identify the unique target, make the right drug, use the right patient
 - Finding the right marker will identify who should get a drug and who shouldn't get a drug
 - Sometimes this happens at the same time, but sometimes this is separated by many years
- Challenges
 - Most cancer therapies do not have predictive markers
 - Most cancer therapies are either modest or transient
 - Tumor growth/survival pathways are adaptive
- Combinations of molecularly targeted agents (MTAs)
- Future directions

Dialogue with the DCLG

- We see increasing awareness for people to pursue or explore combination trials. When CTEP is the broker, we hardly see problems. When a pharmaceutical company has a similar agent, they may want their own drug in the combination. There are some roadblocks, including IP issues, and NCI continues to work on that
- If you have two experimental agents that have never been approved, is the approach different than two agents that you already have a schedule for?
 - We always want to see a single agent first. You have to have at least one trial for each agent

- In the translation from preclinical to clinical, often when we say it doesn't translate, we've not looked at preclinical models carefully. The biology of cell lines does not represent what we see in patients

Facilitating Regulatory Review: What the FDA Wants to See

Dr. Patricia Keegan

- Clinical development programs
 - The ultimate goal is marketing approval
 - FDA looks at net clinical benefit (effectiveness vs. safety)
- Clinical trial efficacy endpoints
 - Depend on drugs mechanism of action, cancer prognosis, available and efficacy of alternate treatments and type of approval sought (regular vs. accelerated)
 - These could include time to response, response duration, time to progression, disease free survival, and overall survival
 - Overall, these are patients living longer or better
 - Surrogate endpoints can also be used
- Combination products
 - It's a challenge when combinations are developed by two companies that do not choose to share information

Dialogue with the DCLG

- What about companion diagnostics makes it necessary to do so much planning prior?
 - You need to know the characteristics of the tissues to get valid results
 - Sometimes in order to improve the device diagnostic, they change the parameter they're testing
- In the future when we have more markers, is there a way to speed things up?
 - The best thing that could be done is developing the scientific basis that is compelling enough that it is obvious prima facie. The more data you have that you think are reliable, you may be able to cut back on the clinical steps. The better it works, the shorter the time is.
- Is the FDA looking at ways to streamline combinations and make them less problematic?
 - Look at the component with the greatest risk and make sure that's covered. You look at the component that you think the greatest risk is, then supplement for other needed items.
- Imaging – recognizing the advances, what can help the FDA and what barriers exist to make imaging a surrogate marker?
 - Imaging markers are not as big a hurdle as other markers. For many of these, what is the information that leads you to believe this is reasonably likely to help someone live longer? For some markers, it's far from what the patient is feeling. The question is how do you have enough evidence to know that an imaging marker is going to make people live longer? How much information do you want

before you say, “this is good enough?” NCI has at least two trials of imaging agents for patient management. We have some trials to get that data.

- Regulatory requirement for necessity of combination – can this be preclinical data?
 - Yes, it depends on how credible your preclinical data is. There is evidence in IL-2 development in combination with LAK.
- How did the development of old chemotherapy go?
 - Some were add-ons. Some are not approved by FDA as combinations. There is a rich history for doing combinations in oncology.
- What can advocates do?
 - Ask to see the data. Even if you don’t understand every piece of it. If people have information, things move quicker. Advocates can ask questions of the companies to see what they’re doing.
 - Ask companies how they’re going to identify the patient population once the drug is approved.
 - Drug companies want the biggest populations possible, but sometimes only start looking after that doesn’t work.
- Advocates want safe drugs, but they also want drugs in people’s hands while they’re alive.
 - Companies must enrich the trials in the right population. Know what their drugs do.
- Accelerated approval – Are there any instances in which companies go for full approval rather than accelerated approval? Are trends going that way?
 - Yes. When we see something that looks really good...sometimes we’ve seen things that we’ve given full approval. This is more common in situations where there’s nothing out there; this is more difficult when there are already agents. When there’s a safety issue where we have to see the overall survival, then it has to go to full approval.

September 23, 2011

Changes Necessary for the Clinical Trials System to take Full Advantage of New Science

The following list of ideas about changes, improvements, and activities that the cancer research community must undertake related to cancer clinical trials in order to capitalize on recent cancer research discoveries. This list was generated by DCLG members during a wrap-up session of the October meeting. To frame the discussion the following questions were posed to members: What needs to change within the current clinical trial system in order to take advantage of new molecular science? What can the advocacy community do to create a broader understanding about the need for change within the clinical trials system and how can it support these changes?

Infrastructure

- Implement a common IT infrastructure for the cancer clinical trials network
- Find ways to match/connect EHRs with cancer clinical research
- Create standards for tumor profiling and characterization technologies

- Standardize tools for tissue collection and patient care across institutions conducting clinical trials
 - Pool resources across the NCI networks
 - Incentivize use of tools and compliance with standards (provide a blueprint with corresponding budget for implementation)

Patient Access and Selection

- Increase patient access to clinical trials
- Increase community oncologists' access to clinical trials system
- Better identify which patients should be enrolled in which clinical trials; as a routine part of the clinical trials process, screen patients for the relevant mutation/target as part of eligibility criteria; larger sample sizes needed than for typical treatment trials
 - Need reimbursement for this screening. What is the true cost of a molecularly driven trial? Need to broaden what is reimbursed as part of a trial
 - Concern of patient fatigue if only 20% are eligible
- Improved understanding of the importance of biomarkers in determining who will benefit from a particular treatment
 - Community needs increased access to testing sites
- Lessen the impact of co-morbidities on patient eligibility
 - Ensure they are necessary, rather than standard exclusions
- Research and develop more reliable diagnostics with clinical utility
 - Patient reimbursement for diagnostic tests
 - SOPs for use of diagnostics in community labs

Science

- Understand the scientific challenges and limitations to drug discovery, particularly drug combinations
 - Consider what non-drug opportunities might be
- Better integrate phase 0 trials into the clinical trial process; expand utilization of this pre-clinical activity
- More closely scrutinize a phase 2 trial before proceeding with a phase 3 trial
 - Look for big patient benefit before moving to phase 3, not marginal results (i.e. have a healthy skepticism of the clinical trial data)
- Improve prioritization of phase 3 trials across all cancer types
- Integrate CBPR principles into the creation, development and conduct of clinical trials

Communication and Education

- Understand trial design options and ask questions. Support researchers in considering all the options and utilizing the most appropriate trial design for each particular study.
 - Promote a better understanding of adaptive trial design and its appropriate use (not a fit for all studies)
- Educate patients about importance of the clinical trial process and their participation.

- Be able to address skepticism
- Understand new clinical trials (biomarker based) and how to explain them to newly diagnosed patients
- Alternatively, savvy patients: Why go on a trial if science is moving faster than clinical trial system?
- Educate IRBs about the patients' perspective on reasonable/relative risk related to tissue collection, testing, and other procedures that have the capacity to inform treatment decisions
 - Address when IRBs are protecting the institution vs. protecting the patient
 - Work with a national organization

NCI Update: NCI Center for Cancer Genomics

Dr. Barbara Wold

- Three goals of the Center for Cancer Genomics (CCG)
 - Formaldehyde fixed paraffin embedded (FFPE) samples
 - Changing the procedure for sample preservation from freezer to FFPE
 - Adopting personalized tumor diagnosis and treatment
 - Prepare patients and their doctors for personal genomics
 - Protect privacy without blocking treatment or research
- Why now? NCI needs to get out in front of this.

Dialogue with the DCLG

- What do you mean by causation?
 - A change in DNA that alters a gene or several changes that alter several genes that causes these cells to be cancerous.
- What is the mindset of the clinicians that are open to genetic testing of tumors vs. those that don't?
 - The community clinician is eager to put new technology into play, but there are many issues in relation to ethics, the healthcare system, payment (do you ask when you know it won't be reimbursed?)
 - Screening for EGFR in France was part of the AstraZeneca drug gefitinib launch (companion diagnostic). There are corporate powers at play here
- How do you see the CCG working with the translational areas of NCI (clinical trials, SPOREs, etc)?
 - Dr. Wold will be talking with cooperative groups around reorganization
- How can CCG help to put their stamp of approval on lab tests not FDA approved?
 - This makes scientific sense. Public-private partnerships may make sense in this instance

NCI Update: Communications Update

Mr. Rick Borchelt

- DCLG advises the Institute on what and how we communicate our messages
 - NCI messaging matrix distributed to senior leadership
 - Getting away from the “War on Cancer” message
 - Letter to NCI director around grantors acknowledging federal funding
 - This led to proposed language that is being sent up to NIH
- New news feed from Cancer Centers into NCI website
- Bypass 2012 will focus on a number of initiatives at NCI, including the new NCI Center for Cancer Genomics, the Center for Global Health, NCI-Frederick, the Provocative Questions RFAs, how and why grants are funded, and NCI-Designated Cancer Centers

Dialogue with the DCLG

- Acknowledging NIH funding is a way to build support for all ICs
- Prevention – is it possible? Should we take it out of our vocabulary? Should we focus on risk reduction?
- There is a lot of stigma surrounding lung cancer, it’s important to be sensitive around prevention and individual causality around cancer.
 - We need better phraseology around chronic and preventable diseases; the DCLG can help craft this
- Global Health – there are populations in this country that are not being reached. The global health message does not resonate with the rural population in the US
 - This is a priority of the NIH and has been since its inception
 - There are some cancers that cannot be studied in this country for various reasons
- Things like NCI-Frederick are not things advocates get excited about
 - There are communities that are interested in that, and that will only be a small part of the bypass
- The bypass isn’t consumable for all audiences, but there are important messages in there. Is there something to disseminate to other audiences?
 - There has been and will be work done by OAR to create bypass collateral for a broader audience
- Be sensitive to those people who can’t afford to get to a cancer center and have to be treated in the community

NCI Update: Advocacy Update

Ms. Shannon Bell

- Financial Conflict of Interest regulations
 - Addressed at the most recent National Cancer Advisory Board (NCAB) meeting
- NCAB notes – Are these useful to the board?
 - Should we engage with other boards in a similar fashion?

- Next meeting in San Francisco (pending approval)
- NCI working on Concise Informed Consent document
- ARWG Implementation
 - Assess and match for advocates
 - Central training repository

The meeting adjourned Friday, September 23, 2011 at 12:30 pm.