

**National Cancer Institute (NCI)
National Cancer Advisory Board (NCAB)
ad hoc Subcommittee on Experimental Therapeutics**

**Gaithersburg Marriott Washingtonian Center
Gaithersburg, MD
11 June 2024
8:00 p.m.–9:00 p.m. EDT**

SUMMARY

Subcommittee Members

Dr. Richard J. Boxer, Chair
Dr. Rose Aurigemma, Executive Secretary
Dr. Nilofer S. Azad (absent)
Dr. Anna D. Barker
Dr. Andrea Hayes Dixon (absent)
Dr. Howard J. Fingert

Ms. Julie Papanek Grant
Dr. Amy B. Heimberger (absent)
Dr. Nikan Khatibi (absent)
Dr. Susan Thomas Vadaparampil (absent)
Dr. Ashani T. Weeraratna (absent)

Other Participants

Dr. John D. Carpten, Chair, NCAB
Dr. James H. Doroshow, NCI
Dr. Shelton Earp, Chair, BSA
Ms. M.K. Holohan, NCI
Dr. Ana Maria Lopez, BSA
Ms. Anne Lubenow, NCI
Dr. Karen M. Mustian, BSA

Dr. Lisa A. Newman, BSA
Dr. Diane Palmieri, NCI
Dr. W. Kimryn Rathmell, Director, NCI
Ms. Joy Wyszneaukas, NCI
Dr. Amanda Cennamo, The Scientific
Consulting Group, Inc., Rapporteur

Welcome and Opening Remarks

Dr. Richard J. Boxer, Clinical Professor, David Geffen School of Medicine, University of California, Los Angeles

Dr. Richard J. Boxer, Subcommittee Chair, welcomed the participants to the *ad hoc* NCAB Subcommittee on Experimental Therapeutics (Subcommittee) meeting. He expressed appreciation to Dr. Rose Aurigemma, Executive Secretary, for her assistance during the past year.

Briefing and Review of Subcommittee's Mission Statement

Subcommittee Members

Dr. Boxer led a group discussion on the Subcommittee's newly drafted mission statement. He stated that his goal in this effort was to define a new vision for the Subcommittee, building on its original charter from 20 years ago. He noted that the new mission statement was intended to be sufficiently broad to encompass all relevant aspects of experimental therapeutics but specific enough to capture important points.

Dr. Boxer emphasized that the NCAB members offer important expertise that NCI can utilize. He suggested that NCAB, and the Subcommittee members in particular, convene a conference or workshop with relevant partners (e.g., academia, private sector, NCI) to share ideas and develop actionable items for

NCI. These efforts will ensure that the community is working in a consistent direction, which will ultimately benefit cancer patients.

Discussion and Concurrence on Mission Statement

Subcommittee Members

Dr. Aurigemma invited the participants to provide comments on the draft mission statement. Dr. Howard J. Fingert suggested that the Subcommittee consider the mission statement's meaning across different contexts. He remarked that he is interested in the contexts of regulatory science and drug development tools. Dr. Fingert also noted that regulatory science offers opportunities for cost savings; he suggested that the Subcommittee consider this perspective as a part of its mission. He clarified that he was not proposing substantive changes to the mission statement, but he requested that the Subcommittee reach an agreement on the meaning of the existing wording.

Dr. John D. Carpten, NCAB Chair, suggested that the Subcommittee consider the topic of artificial intelligence (AI)/machine learning (ML), with a focus on NCI's role in leading progress in this area at a national level. Dr. Carpten remarked that AI/ML offers potential across the full continuum of drug development, including clinical trial design. Ms. Julie Papanek Grant added that AI/ML technologies can be beneficial for identifying quality control issues within databases.

Dr. Lisa A. Newman noted that the lack of diversity in cancer research data must be considered, particularly in the context of AI/ML. Dr. Ana Maria Lopez suggested that the mission statement be revised with language on the community served. She added that this exercise provides opportunities for the Subcommittee to consider these topics more broadly and review new scientific concepts and digital tools.

Dr. Anna D. Barker suggested that the Subcommittee consider the most effective approaches to make the greatest impact in drug development. She noted that small private companies often lack the resources for progress in this area. Currently, many companies are focused on developing new drugs that build on previously developed agents. Dr. Barker asked the Subcommittee to consider how NCI can support these companies. She also asked whether the Subcommittee will focus primarily on drug development or drug discovery.

Dr. Aurigemma remarked that the mission statement was written to enable collaborations with NCI's Division of Cancer Control and Population Sciences, as well as the Center for Biomedical Informatics and Information Technology, which oversees NCI's AI efforts. Dr. Barker suggested adding language clearly stating that the Subcommittee considers barriers and problems in both drug discovery and development.

Dr. Aurigemma commented that the mission statement could include broad language about emerging technologies. Dr. Lopez suggested language to incorporate a focus on the community served. Dr. Fingert noted that a prior version of the document included a reference to quality, which has represented a long-standing challenge in cancer research. The Subcommittee members agreed to conditionally approve the mission statement, with language on community service included.

Focus Areas of Interest and Future Agenda Items

Dr. Boxer and Subcommittee Members

Dr. Aurigemma noted that Dr. Diane Palmieri, Director, Center for Research Strategy, NCI, was invited to this meeting to share her perspective on NCI's activities across different areas of research.

Dr. W. Kimryn Rathmell, Director, NCI, added that the Subcommittee can participate in discussions on increasing efficiency, bridging regulatory science, and developing the workforce.

Dr. Lopez noted that NCI held a workshop in 2021 focused on natural products in drug development. She underscored the value of discussions focused on how NCI can support better science and complex analyses. Dr. Aurigemma suggested that the Subcommittee develop a list of topics of interest, which then can be reviewed against NCI's current efforts in those spaces.

Dr. Carpten wondered whether the Subcommittee would benefit from additional experts in the areas of interest. Dr. Aurigemma clarified that *ad hoc* members cannot be added to the Subcommittee, but NCI colleagues can attend the meetings. Other experts can be included in workshops as guest speakers. Dr. Grant suggested engaging more representatives from small biotechnology companies in the discussions. Dr. Fingert commented that the Small Business Investor Alliance has participated in discussions with federal agencies in this area. Dr. Aurigemma emphasized that NCI relies on the Subcommittee's guidance in bringing in other experts and perspectives.

Dr. Grant reiterated that AI/ML will remain a critical topic in this space. She emphasized that the Subcommittee plays an important role in obtaining funding and capturing public interest in NCI's research portfolio. Dr. Fingert added that AI/ML methodologies can serve as a valuable resource; he emphasized the importance of expertise in quality and best practices. Dr. Rathmell replied that NCI is interested in leveraging community experts and addressing current needs in this space.

Dr. Fingert commented that other investments (e.g., NCI Experimental Therapeutics [NExT] Program) can be leveraged where appropriate. Dr. Aurigemma noted that NCI organized a virtual workshop several years ago focused on drug discovery and development, with discussions on AI/ML technologies. She noted that the discussions could be expanded in future workshops.

Dr. Grant suggested engaging with representatives from Microsoft to discuss capabilities of future large language model releases. These discussions could represent partnerships between NCI and the technology industry, with a forward-looking roadmap on AI/ML technologies and capabilities for cancer research. She commented that AI/ML has been most effective in activities focused on words; protocols and databases are particularly relevant in this context.

Dr. Grant noted that clinical trials management is experiencing a national labor shortage. Additionally, labor represents a major cost in clinical trials. AI/ML could help bridge this gap; Dr. Grant suggested that this topic be considered as a focus area, with an emphasis on currently relevant applications. She noted that this topic also can be considered in the context of reconciling quality throughout the process.

Dr. Barker cautioned that the data must be high quality for AI/ML tools to be useful and effective. Dr. Fingert suggested adding language on quality to the mission statement. Additionally, several Subcommittee members commented on the need to raise community awareness of NCI's activities and accomplishments.

Adjournment

Dr. Aurigemma thanked the participants for their engagement during the meeting and noted that she will provide materials from past NCI workshops focused on drug development and other relevant topics. She adjourned the meeting at 9:04 p.m. EDT.

Dr. Richard J. Boxer
Chair

Date

Dr. Rose Aurigemma
Executive Secretary

Date