

# **Implementation Status Plans for NCTN WG Cross-Portfolio Recommendations**

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# Cross-Portfolio Recommendations

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- **Emphasize Innovative Science Driven Trials**
- **Consider Reallocation of NCTN Resources**
- **Enhance Coordinated Strategic Planning**
- **Strengthen Evaluation Criteria**
- **Optimize Steering Committee Processes**

# Emphasize Innovative Science Driven Trials

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NCI, NCTN Groups, CCOP Research Bases, and Steering Committees should work together to achieve the appropriate balance of innovative, biology-driven randomized phase 2 trials and larger, more resource intensive phase 3 trials in each disease portfolio

## NCI Implementation Activities

- Proactively communicated message to the NCTN Groups and the Steering Committees
- Focus on the appropriate balance of innovative and more conventional trials when establishing strategic priorities for each disease
- Monitor performance through periodic strategic assessment of clinical trial portfolios

# Emphasize Innovative Science Driven Trials

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NCTN Groups, CCOP Research Bases, and Steering Committees should emphasize biology-driven (e.g., molecularly-driven, pathway-driven) trials that advance the science by incorporating genomics, biomarker tests and correlative science into study designs

## NCI Implementation Activities

- Proactively communicated message to the NCTN Groups and the Steering Committees
- Focus on biology driven trials when establishing strategic priorities for each disease
- Monitor performance through periodic strategic assessment of clinical trial portfolios
- Scientific impact/contribution a primary criterion for cross-disease prioritization

# Consider Reallocation of NCTN Resources

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NCI, working with the extramural community should conduct an analysis of resource allocation across diseases, taking into account current survival rates and likely cost/benefit from additional advances

## NCI Implementation Activities

- Extramural discussions did not support upfront budget allocation to each disease, concluding allocation should be driven by the science
- Cross-disease prioritization of resource-intensive trials will consider current resource allocations

# Consider Reallocation of NCTN Resources

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To empower innovative, biology-driven trials, additional NCI funding should be provided for correlative science studies, biomarker validation and the development of molecular classification algorithms

## NCI Implementation Activities

- NCI has set aside funds annually for the Biomarker, Imaging, & Quality of Life Studies Funding Program (BIQSFP)
- Creative partnerships (e.g., Foundation for the NIH (FNIH), philanthropy, and industry partners) may provide new resources for integral, integrated and correlative studies
- R21 grant mechanism can be used to fund innovative correlative studies

# Enhance Coordinated Strategic Planning

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Steering Committees should increase their involvement in strategic planning and guidance for future trials in collaboration with the NCTN Groups, the CCOP Research Bases, and NCI

## NCI Implementation Activities

- Continue to implement through Clinical Trials Planning Meetings
- Implement through the new disease-specific strategic priority setting process

# Enhance Coordinated Strategic Planning

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Greater emphasis should be placed on sharing strategic and tactical best practices across diseases in terms of trial design, accrual, preliminary data requirements, etc.

## **NCI Implementation Activities**

- Periodic strategic assessment of NCTN trial portfolios will provide a regular venue for sharing best practices

NCI, NCTN Groups and Steering Committees should continue to pursue collaborations with international and industry partners and address barriers to these collaborations

## **NCI Implementation Activities**

- Public-private partnerships (e.g., LungMaP trial) provide a novel template that may be useful for future collaborative trials



# Strengthen Evaluation Criteria

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More attention should be paid to accrual challenges in proposing and approving trial concepts, balancing the importance of the clinical question with the perceived difficulty of accrual

## NCI Implementation Activities

- Proactively communicated message to the NCTN Groups and the Steering Committees
- Accrual challenges currently part of evaluation criteria, but importance is being emphasized
- Accrual performance being carefully monitored by CTEP

# Strengthen Evaluation Criteria

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More consideration should be given to competing international and industry trials in proposing and approving trial concepts

## NCI Implementation Activities

- Proactively communicated message to the NCTN Groups and the Steering Committees
- Competing trials currently part of evaluation criteria, but importance is being emphasized
- Competing trials a criterion for cross-disease prioritization

# Strengthen Evaluation Criteria

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Steering Committees should develop guidelines for the level and types of preliminary data required for trial concepts

## NCI Implementation Activities

- NCTN Groups, Steering Committees and NCI will work together to develop disease-specific guidelines for preliminary data requirements
- Monitor implementation through periodic strategic assessment of clinical trial portfolios

# Optimize Steering Committee Processes

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SSCs should optimize their use of Task forces, Working Groups and Clinical Trial Planning Meetings (CTPMs)

## NCI Implementation Activities

- Proactively communicated message to the NCTN Groups and the Steering Committees
- Monitor use through periodic strategic assessment of clinical trial portfolios

# Thank You