# Implementing a National Cancer Clinical Trials System for the 21st Century

Institute of Medicine

American Society of Clinical Oncology

## Patient Advocate Perspectives:

## Grabbing The Brass Ring

# The Cooperative Group System Is A National Treasure

We need be both bold and careful as we move forward to make it better

…Because breaking it would be a tragedy for all cancer patients, present and future

**“I worry that the man who invented Muzak might be thinking of inventing something else.”**

Lily Tomlin

# This Is Not The First Time The System Has Been Re-Invented

- Previous efforts have been fraught with false starts, unintended consequences and stillborn constructs
- We are all older and wiser and much has been learned
- But, we should expect that there will be issues as this effort moves forward and we need to keep an open mind and be ready to fine tune the strategy and implementation

# There Are Hopeful Signs

- Much has been learned in recent efforts to improve the system and there are numerous examples of ways to get concrete results:
  - New rules for protocol development timeframes
  - CIRB parallel approval process and process improvement
  - More stringent data monitoring
- IOM has taken a zero-based approach that makes bold recommendations for structural change that have driven clear mandates from NCI
- There is recognition that the transition will be costly and will require significant incremental resources

# …But Management Of These Efforts Lacks The Rigor That Is The Glory Of Our Trials

- Single-armed, ambiguous schema
- No explicit "dose modification schedule"
- Overabundance of surrogate endpoints that are very logical but don't necessarily engender tangible benefit (e.g., four groups vs. ten, single committee vs. multiple committees for a disease)
- Ambiguous data monitoring plan

# On Behalf Of My Fellow Patients: …Please:

- Define what constitutes success in terms of concrete endpoints and timeframes
- Include some tangible patient and scientific outcomes as endpoints
- Put in place instrumentation, transparency, and accountability in this implementation (i.e., clear metrics with targets and timeframes)
- Be quicker to course-correct/adapt, be more flexible than in prior implementations

I'd like to close with a politically-incorrect question…

# Why Is There Only One Patient Advocate on this workshop's agenda?

- There are over 40 invited speakers/panel participants
- 1-2 leaders of each of the groups is here, a total of 16
- There are almost 100 advocates working within the groups and each of the 10 groups has an advocate chair, yet only one advocate was invited to speak
- There was only one advocate on the IOM task force, which had over 25 members, and this advocate was not a cooperative group advocate
- On behalf of the patient community, I ask that this not be the model for the implementation
- The Cooperative Group Advocates have much to offer and no one has more at stake than we do-- We want to be involved