



# A201501 Phase II Dignity Therapy / Life Plan in Patients with Pancreatic or Advanced Lung Cancer: Lessons learned from concept submission

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Ann Marie Dose, PhD, RN, ACNS-BC, ACHPN

Mayo Clinic

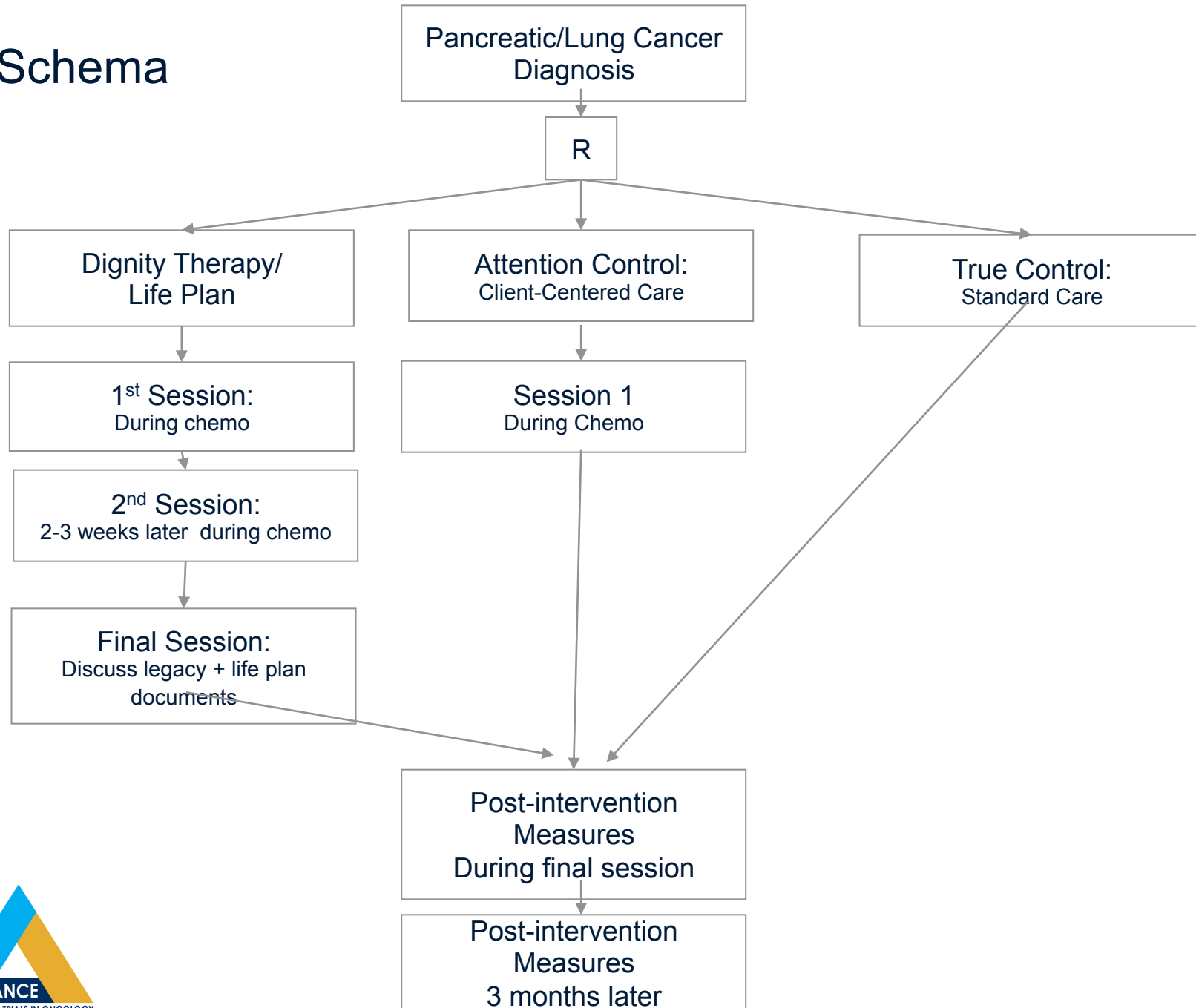
Alliance Health Outcomes Committee Meeting

May 14, 2016

# Presentation Objectives

- Discuss disapproval issues related to this concept proposal submission Dec. 2015
- Explore future strategies for concept proposal submissions

# Schema



# Issues identified during review

- Scientific/Design Issues

- Inadequate literature synthesis – ID strengths/weaknesses of prior research
- Inadequate rationale for moving intervention from hospice setting to active treatment setting
- Contamination from those already receiving palliative care
- Cross contamination across study arms
- Overlapping questionnaires

# Issues - Feasibility

- Concerns about time commitment for intervention and study coordination
  - “The investigators’ belief that the cancer control credit will cover the training and intervention is incorrect. Cancer control credit supports data management; in this case, the collection of patient reported outcome data and transferring that data to the Alliance data management center.”
  - “Additional resources would be needed to cover the costs of training and the interventionists’ time.”

# Issues - Feasibility

- The definition of the primary endpoint criterion for recruitment feasibility is faulty
  - % vs. numbers recruited/year
- Given “negative results of previous studies” ....
  - Not true – actually mixed results
- In summary, the Committee believes that dignity therapy has the potential for improving the quality of life in patients experiencing high distress”

# Next steps

- Submitting R21 to NINR
- More exploratory aims – logical next step

# Conclusion

- Questions
- Discussion