

# Returning Clinical Trial Results to Patients

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# What clinical trial participants want know

- What were the results of the trial in which I participated?
- How are the results being used?
- Did my participation make a difference?
- What do the clinical trial results mean for me?

# Patients as Partners in Research

- Opportunity to learn about the results of the studies in which they participated
- Plain language aggregate study results and references to publications and presentations
- Encouragement to speak directly to their doctors to learn more about how the study results might affect them
- Appreciation for their participation and its impact on future research

# In conversation with advocates...

- “As a social worker who works with hundreds of patients yearly, I continually hear from participants in clinical trials how much they would like to see results. There is an overall feeling of being dismissed or invisible when one never hears the results.”
- “Personally, I have participated in several trials and never heard results. I think that any participant would want to know the results of their efforts.”
- “If we are able to explain the importance of a trial, then we also have to believe that those patients can understand the results.”
- “Patients are, through participating, working with researchers to find answers and want to know the results of their work.”

# What is happening now?

- CALGB
- ECOG
- IBCSG
- Australia/New Zealand Breast Cancer Trials Group
- Investigators – mostly observational trials involving behavioral or lifestyle interventions
- Institutional – Very little

# DF/HCC Breast Cancer Advocates

- 16 breast cancer patients/survivors interested in research related issues
- Created 5 years ago for NCI funded breast cancer SPORE
- Mission is to support and enhance the work of the DF/HCC investigators by providing an informed patient perspective
- Meets monthly or more as needed
- Currently developing a project for returning the results to patients

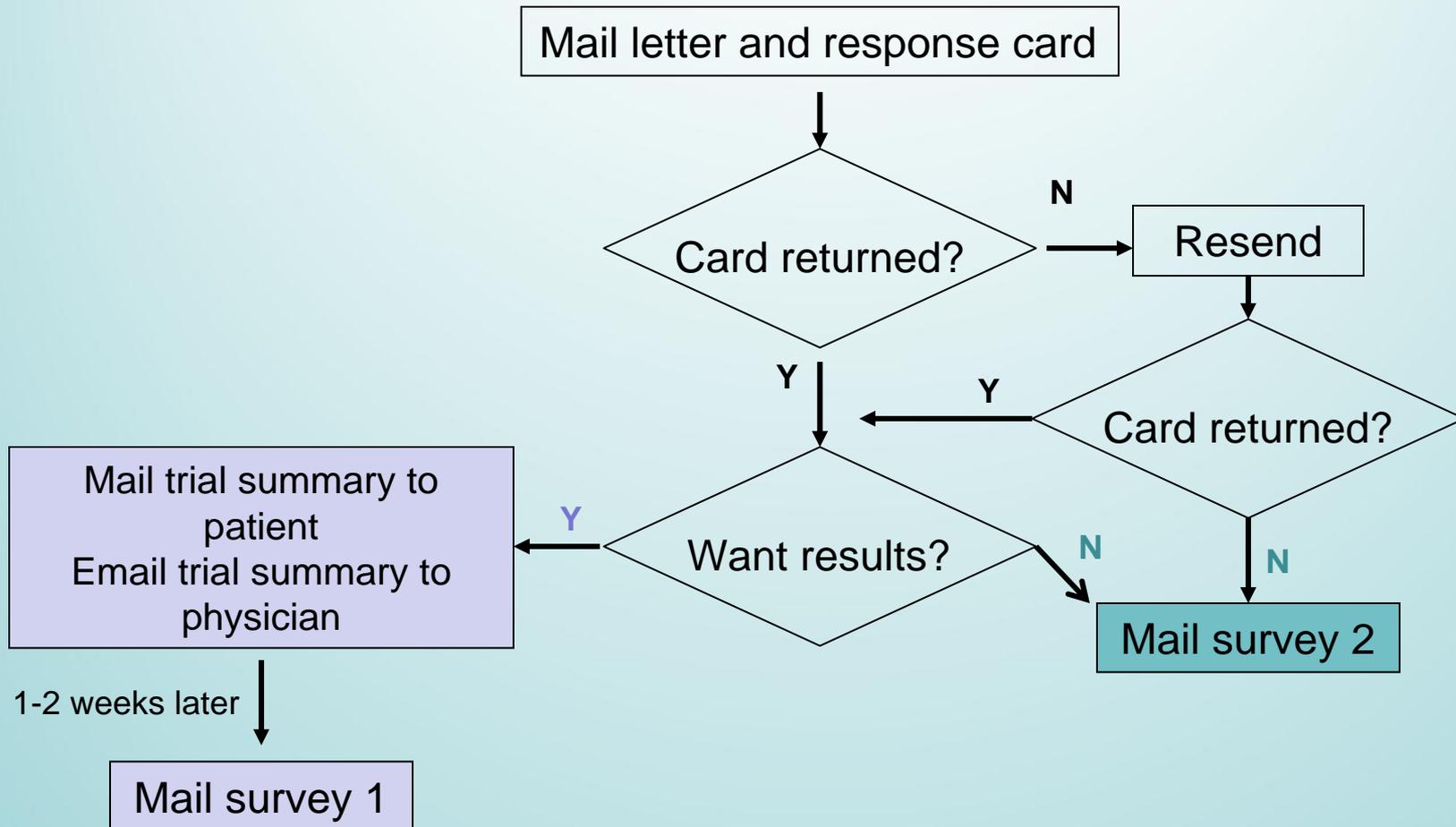
# Pilot Study Goals

- Communicate Gratitude
- Develop a protocol for returning results to participants
- Evaluate the process and materials on a selected trial
- Analyze participant responses
- Estimate time and costs associated with extending the program to all trials

# Pilot Study Materials

- Letter(s) asking participants if they would like to receive results, including a response card with possible opt-out
- Results Summary with Cover Note
- Email to treating physician stating that summary was sent out to their patient
- Survey to participants receiving results
- Survey to participant not receiving results

# Pilot Study Design



# Survey 1 Questions

- From those who received Results Summary:
  - How much of it did you read
  - How easy to understand
  - Completeness of information
  - Missing information

# Survey 2 Questions

- Participants who did not receive results:
  - Reasons for not requesting results
  - Offer to resend summary

# Both Surveys

- Impressions of letter offering trial results summary
- Satisfaction with method of asking for results summary
- Alternative preferences for ways to respond to offer
- Ease in remembering trial
- Rating of overall experience in trial
- Interest in learning trial results
- Expectation of learning trial results

# Both Surveys

- Concern/worry about learning trial results
- Likelihood of participating in another trial
- Likelihood of recommending trial participation to someone with cancer
- Belief that patients should be offered trial results
- Belief that family members should be offered trial results
- Demographics

# Next Steps

- Develop protocol for IRB approval
- Conduct pilot study
- Revise for higher risk population
- Institutionalize the program
  - All trials
  - Consent

# Challenges

- Getting everyone on board
- Developing appropriate and accurate materials
- Finding a clinical collaborator within the institute
- Financial resources

# Costs and Benefits

- Costs
  - Staff time and salary
  - Materials development
  - Investigators (pre and post)
  - Clinical trial participants
- Benefits
  - Current clinical trial participants
  - Future clinical trial participants
  - Investigators
  - Clinical trials process
  - Public

# Conclusions

- Recognizing patients as partners requires a concerted effort
- Participants should be given the opportunity to learn of their contribution to research
- Participants should feel appreciated for volunteering to be in clinical trials

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