Non-Profit Perspective on Patient Centeredness in Clinical Trial Design – OCTOBER 2023

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No Disclosures

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Focus on what is important to patients when participating in a clinical trial

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PATIENTS WANT TO LIVE LONGER

Improve Overall Survival with new therapies

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PATIENTS WANT TO LIVE BETTER

Translate what "improved RR and PFS", reported in clinical trials mean to a patient living life:

- Fewer hospital admissions:
  - biliary obstruction and sepsis
- Avoid things that lower ECOG status
- Able to remain on effective therapy
- Able to remain/return to work
- Quality Time with family, friends, etc.

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PATIENTS WANT TO LIVE BETTER

Live Better on Treatment

- Access to active novel treatments within clinical trials
  - without having to fail standard of care
- Acceptable level of toxicity
- Holistic approach
- Accessibility to new treatments

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PATIENTS WANT TO FEEL SOME SENSE OF CONTROL

Over a situation that feels completely out of control

- Provide hope
- Education of breadth of treatment options
- Support/validate their decisions
- Ability to access drug if mixed response
    - if provider & patient feel there is continued benefit
- Enable them to participate
    - Financial resources so they can participate
    - More decentralized trial options
    - Drug available upon completion of trial

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PATIENTS WANT KNOWLEDGE

Meaningful use of personal health data

- Purpose of their data in a study
- Reporting back
- Improve their ability to access/participate in appropriate clinical trials
- Leveraged to create synthetic control arms
- Patient-empowered research
- Ensuring patient-level data from clinical trials is available for further research

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PATIENTS WANT THE OPPORTUNITY TO PARTNER IN RESEARCH

- Patient-Centered from concept to final protocol
  - Input early and often
- Access: broader inclusion/exclusion criteria
- Acceptable trial design (cross-over arm, 2:1 randomization)
- Informing patients/caregivers of results, thank you
- Dissemination of results widely/community
- Willingness to share surplus samples with researchers (with appropriate consent and approvals)

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SURVEY

- 46 question survey conducted in 2019
- Sent to patient membership of the Pancreatic Cancer Action Network (PanCAN) and Cholangiocarcinoma Foundation (CCF)
- 1,011 patients completed the survey

PANCREATIC CANCER ACTION NETWORK

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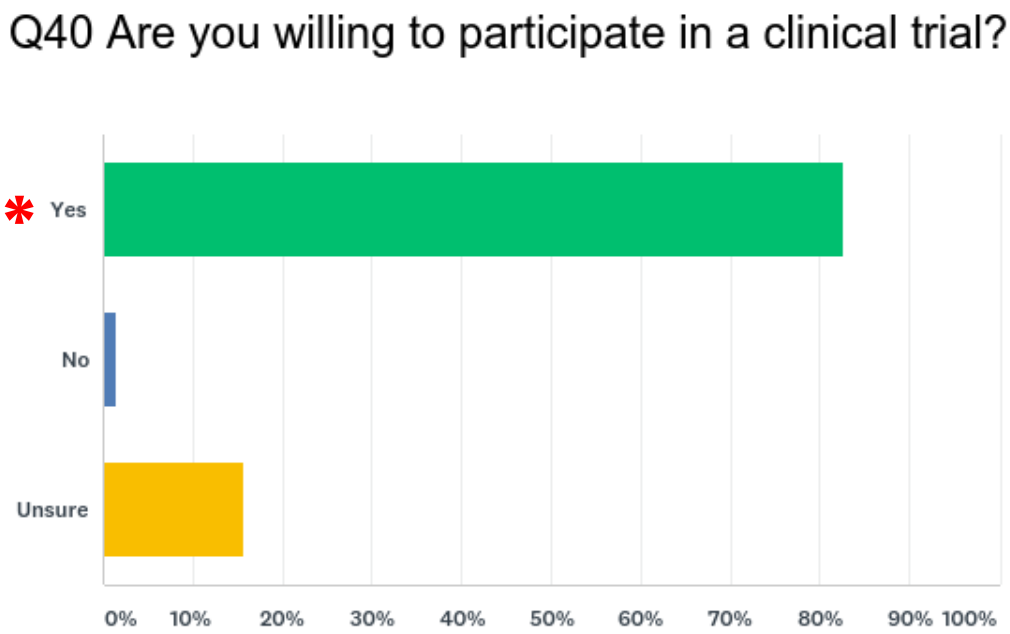
SURVEY RESULTS



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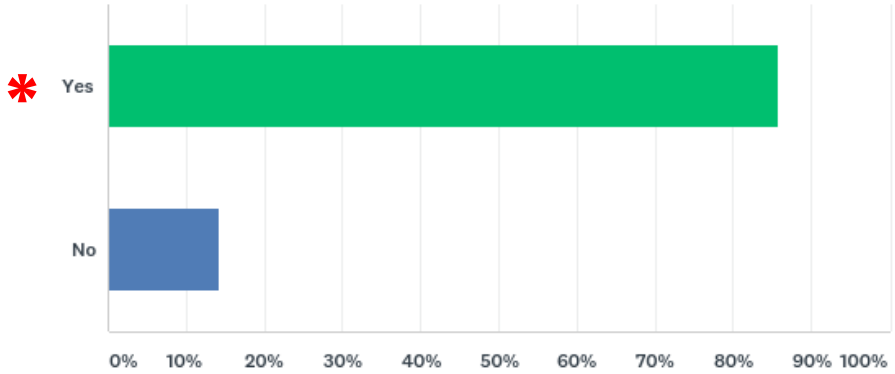
SURVEY RESULTS

Q42 Would you enter into a clinical that has high risk but the potential for better outcomes?



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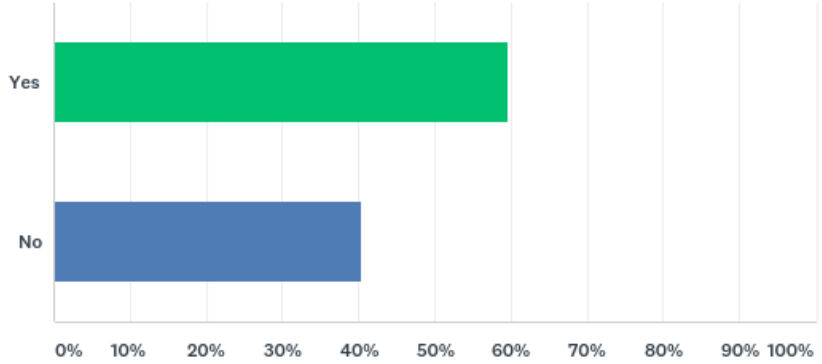
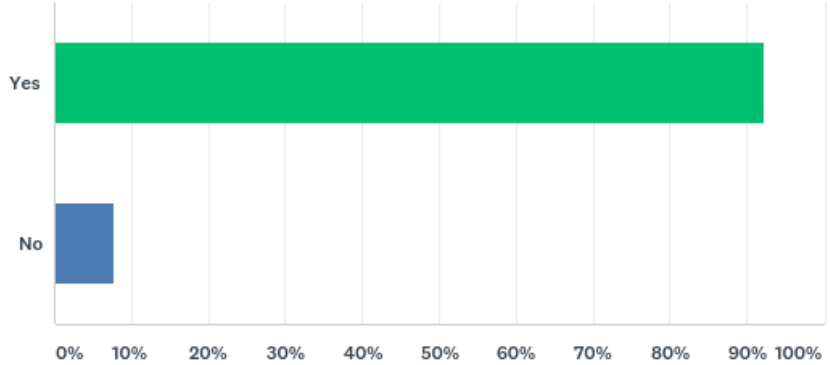
SURVEY RESULTS

Q43 Are you willing to participate in a Phase 1 clinical trial where the dose, safety and toxicity of a new drug is being tested often for the first time in humans?



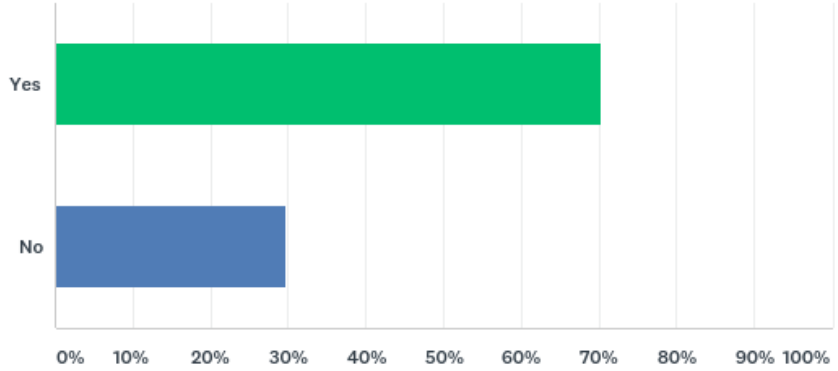
SURVEY RESULTS

Q44 Are you willing to participate in a Phase 2 clinical trial where a new drug is being tested for how well it “treats” your cancer either alone or when combined along with the standard of care (widely used and accepted treatment for a specific disease)?



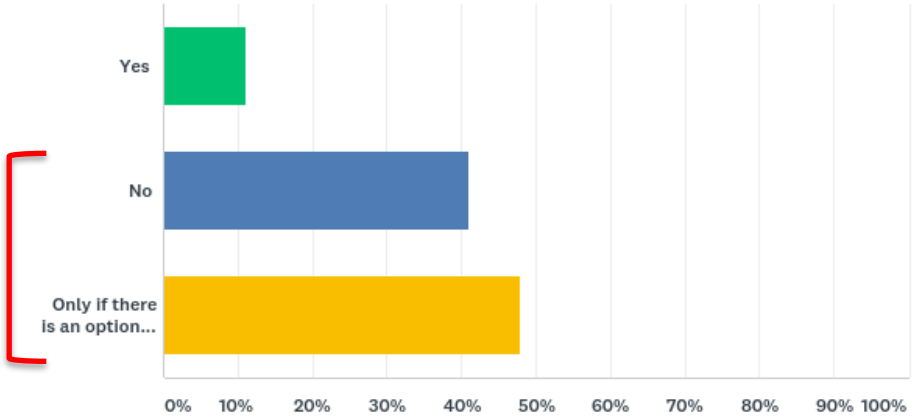
SURVEY RESULTS

Q45 Are you willing to participate in a Phase 3 clinical trial where you would be randomly chosen to receive either the standard of care or an experimental drug?



SURVEY RESULTS

Q46 Would you be willing to participate in a clinical trial even if you receive a placebo ("sugar pill")?



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If I can answer any questions, please feel free to reach me at:

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