A Common Sense Oncology Values-to-Action Framework for Patient-Centered Randomized Trials in Oncology

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COMMON SENSE
ONCOLOGY

Abstract #2029

BACKGROUND

- Despite advances in oncology, too many randomized clinical trials (RCTs) fail to answer the most meaningful question: *does this intervention improve the lives of people with cancer?*
- Many trials prioritize regulatory approval pathways, rely on surrogate endpoints with limited patient relevance, and impose burdensome protocols that deter participation—particularly from underrepresented populations.
- With global patient engagement and leadership, we have developed a framework to guide the design and conduct of oncology trials.

METHODS

Phase 1 – Developing the Framework

- We conducted a scoping review of published and grey literature, patient rights charters, and existing frameworks to identify gaps in patient-centered trial guidance.
- A draft framework was developed through thematic synthesis by 2 authors and revised in collaboration with an international working group.

Phase 2 – Stakeholder Feedback

- After an initial pilot in New Zealand, 7 virtual focus groups were held between Apr 2024 and Jan 2025 with individuals affected by cancer across India, the United States, Canada, Europe, South Africa, Kenya, Ghana, Nigeria, and Brazil.
- Prior to each session, participants received a survey assessing the importance of each value and associated action on a 9-point Likert scale (1 = least important, 9 = most important), along with opportunities for open-text comments.

Phase 3 – Finalizing the Framework

- Quantitative analysis included descriptive statistics and non-parametric group comparisons by age, gender, region, and income level.
- Thematic analysis of qualitative data from survey comments and discussion transcripts was used to iteratively revise the framework.

RESULTS

- A total of 72 responses were received across 7 focus group sessions (Table 1).
- Very strong agreement across all values and actions (median = 9) (Figure 1).
- The action with the lowest median score (*restrictive exclusion criteria*) was given a median score of 8 and had the highest frequency (18%) of neutral responses (scores 4-6).
- Very few items were rated "not-important" (scores 1-3).
- Main themes from qualitative analysis included:
  - The importance of meaningful endpoints
  - Transparent communication
  - Equitable inclusion
  - Fair compensation
  - Plain-language informed consent.

Characteristic	n (%)
Gender	
Female	52 (72.2%)
Male	18 (25.0%)
Missing	2 (2.8%)
Age	
<45 years	13 (18.1%)
45-64 years	31 (43.1%)
≥65 years	26 (36.1%)
Missing	2 (2.8%)
Country of residence	
Brazil	10 (13.9%)
Canada	15 (20.8%)
Ghana	1 (1.4%)
Greece	1 (1.4%)
Guyana	1 (1.4%)
India	15 (20.8%)
Nepal	1 (1.4%)
South Africa	5 (6.9%)
United Kingdom	3 (4.2%)
United States	19 (26.4%)
Missing	1 (1.4%)
Connection to cancer	
Survivor	36 (50%)
Living with metastatic cancer	9 (12.5%)
Family member	9 (12.5%)
Other*	16 (22.9%)

Table 1: Participant characteristics post-pilot. * Patient advocates, people undergoing cancer treatment who may not self-identify as a cancer survivor.

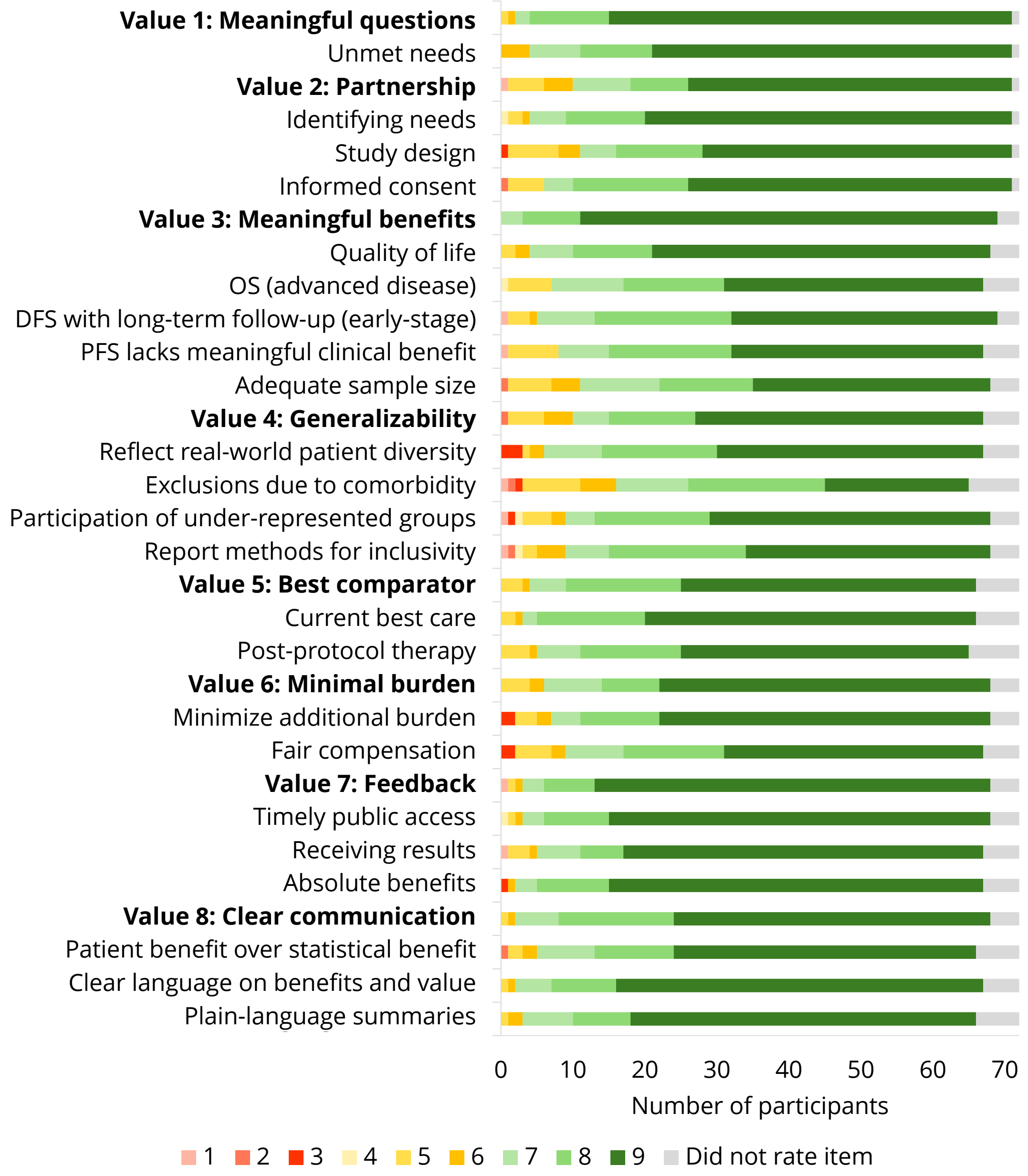

Figure 1: Stacked bar representation of the 72 participant responses to the initial framework on a 9-point Likert scale (1 = least important, 9 = most important).
* Value 2 was later split into two distinct values (partnership, and informed consent), and therefore numbering was altered in the final framework.

CONCLUSIONS

- **Patients strongly support trial endpoints that reflect real-world impact**, including overall survival and quality of life, over surrogate markers such as radiographic response.
- Our framework reflects a **broad, international consensus on what constitutes a patient-centered oncology trial**, including a strong emphasis on co-design, consent, and broad inclusion criteria.
- The resulting framework can serve as a **practical guide for patient advocates** involved in reviewing trials as well as trialists, ethics committees, funders, and regulators.
- This work is especially relevant to the breast cancer field, where advocates have long influenced research priorities and trial design. The framework can help extend this impact globally.

FINAL FRAMEWORK

Meaningful Questions

a. Define unmet needs

Partnership

a. Co-design with patients
b. Involvement at all stages
c. Informed participation

Consent

a. Participant understanding
b. Plain language
c. Ongoing updates

Meaningful Benefits

a. Quality-of-life
b. Endpoint Validation
c. Follow-up
d. Reporting OS
e. Appropriate Sizing

Generalizability

a. Representative sample
b. Minimize exclusions
c. Inclusive participation
d. Reporting on inclusivity

Best Comparator

a. Standard of care
b. Post-protocol therapy
c. Standardization of care
d. Crossover when appropriate

Minimal Burden

a. Trial-related procedures
b. Compensation

Feedback

a. Dissemination to participants
b. Accessible results
c. Communicating benefits

Clear Dissemination of Results

a. Public reporting

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- Common Sense Oncology is a movement of 2500 oncology care providers, patient advocates, and researchers dedicated towards ensuring cancer care and research reflect outcomes that matter to patients.
- Become a member of CSO for free at commonsenseoncology.org

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