Targeted Approach to Improve Diversity in Phase I Oncology Clinical Trials: A Single Institution Experience at the University of Colorado Cancer Center

Ahmed Alsafar, Sama Kareem, Bradley R. Corr, Christopher Lieu, Breelyn Wilky, S. Lindsey Davis, D. Ross Camidge, Antonio Jimeno, Andrew Nicklawsky, Jessica D. McDermott, Jennifer R. Diamond

University of Colorado
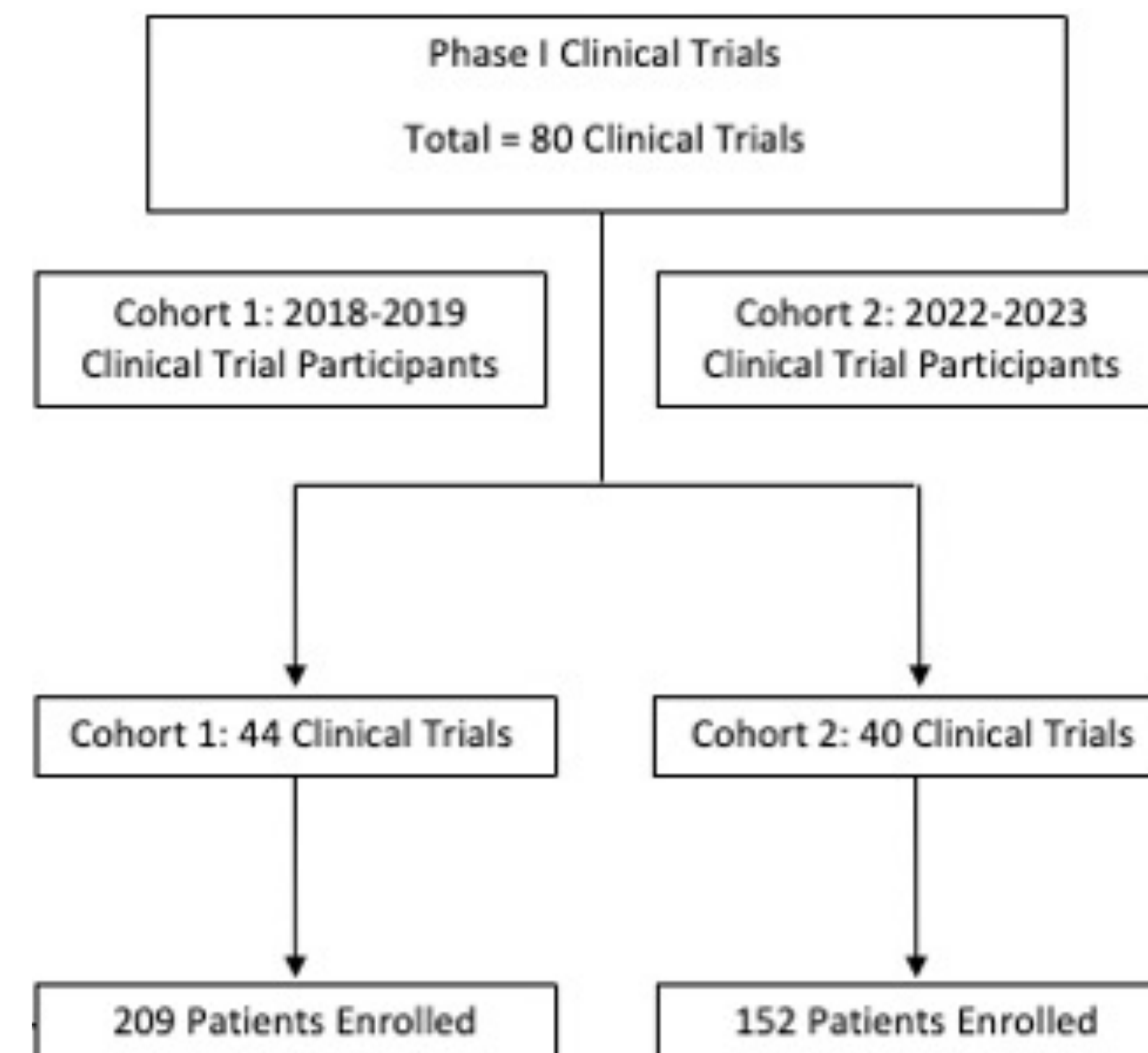Anschutz Medical Campus

Background:

- Both cancer incidence and mortality have dropped since the early 1990s, but disparities persist between racial, ethnic, and socioeconomic groups.
- One potential driver is the lack of appropriate representation in clinical trials, including dose-finding studies.
- There are individual level barriers and systemic barriers that hinder patient participation in clinical trials including patient mistrust, health literacy, added cost, clinician perceptions, language barriers, and restrictive clinical trial designs.
- We implemented a set of initiatives including multilingual educational videos, outreach to other health systems, a Spanish-speaking bicultural clinic, and regular reviews of patient accrual and goals.
- Objective: Compare Phase I clinical trial demographics before and after the implementation of our interventions.

Methods:

- Retrospective review of patients enrolled in 2018-2019 (cohort 1, pre- intervention) and 2022-2023 (cohort 2, post-intervention).
- Socioeconomic disadvantage status was estimated using the area deprivation index (ADI) tool.
- Progression-free survival (PFS) and overall survival (OS) were calculated using the Kaplan-Meier method.

Results (Demographics):

- Increase in language preference other than English from 1.91% to 6.58% (p = 0.028) and in translated consents from 1.44% to 5.92% (p = 0.033).
- No statistically significant difference in race, ethnicity, insurance, or tumor type between Cohorts 1 and 2.

Phase I Clinical Trials

Total = 80 Clinical Trials

Cohort 1: 2018-2019 Clinical Trial Participants

Cohort 2: 2022-2023 Clinical Trial Participants

Cohort 1: 44 Clinical Trials

Cohort 2: 40 Clinical Trials

209 Patients Enrolled

152 Patients Enrolled

Variable and p-value		Cohort 1:	Cohort 2:
Race 0.2786	White	176 (84.21%)	131 (86.18%)
	Asian	7 (3.35%)	5 (3.29%)
	Black or African American	5 (2.39%)	0 (0%)
	More Than One Race	1 (0.48%)	3 (1.97%)
	Native Hawaiian or Other Pacific Islander	1 (0.48%)	0 (0%)
	Unknown / Not Reported	19 (9.09%)	13 (8.55%)
Ethnicity 0.352	NOT Hispanic or Latino	192 (91.87%)	135 (88.82%)
	Hispanic or Latino	17 (8.13%)	16 (10.53%)
	Unknown / Not Reported	0 (0%)	1 (0.66%)
Preferred Language 0.0284	English	205 (98.09%)	142 (93.42%)
	Other	4 (1.91%)	10 (6.58%)
Translated Consent Use 0.033	No (English)	206 (98.56%)	143 (94.08%)
	Yes	3 (1.44%)	9 (5.92%)
Health Insurance Status 0.3683	Medicare	89 (42.58%)	76 (50%)
	Private Insurance	101 (48.33%)	60 (39.47%)
	Medicaid	18 (8.61%)	15 (9.87%)
	Uninsured	1 (0.48%)	1 (0.66%)

Results (Survival):

- Median PFS was 2.83 months in cohort 2 compared to 1.91 months in cohort 1 (Hazard Ratio (HR) = 0.72, p<0.01)
- In the subset of colorectal patients, ADI scores of 6-10 were associated with worse PFS and OS (p = 0.022 and p = 0.001, respectively) compared to ADI scores of 1-5.

Discussion:

Our set of interventions led to an increase in accrual of non-English speaking patients and translated consent use.
Higher ADI scores, indicating less affluent neighborhoods, correlated with worse outcomes in patients with colon cancer.

Implications:

1. Socioeconomically-disadvantaged patients continue to have worse treatment outcomes on phase I clinical trials.
2. Targeted interventions can successfully improve accrual of populations historically-underrepresented in research.

Limitations:

- Single institution study.
- Confounders: wide range of tumor types, clinical trial drugs with varying efficacy as well as social factors not readily available in medical record systems.

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