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ORIGINAL ARTICLE

Allocation of authorship and patient enrollment among global clinical trials in oncology

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Abstract

Background: Oncology randomized controlled trials (RCTs) are increasingly global in scope. Whether authorship is equitably shared between investigators from high-income countries (HIC) and low-middle/upper-middle incomes countries (LMIC/UMIC) is not well described. The authors conducted this study to understand the allocation of authorship and patient enrollment across all oncology RCTs conducted globally.

Methods: A cross-sectional retrospective cohort study of phase 3 RCTs (published 2014–2017) that were led by investigators in HIC and recruited patients in LMIC/UMIC.

Findings: During 2014–2017, 694 oncology RCTs were published; 636 (92%) were led by investigators from HIC. Among these HIC-led trials, 186 (29%) enrolled patients in LMIC/UMIC. One-third (33%, 62 of 186) of RCTs had no authors from LMIC/UMIC. Forty percent (74 of 186) of RCTs reported patient enrollment by country; in 50% (37 of 74) of these trials, LMIC/UMIC contributed <15% of patients. The relationship between enrollment and authorship proportion is very strong and is comparable between LMIC/UMIC and HIC (Spearman's ρ LMIC/UMIC 0.824, $p < .001$; HIC 0.823, $p < .001$). Among the 74 trials that report country enrollment, 34% (25 of 74) have no authors from LMIC/UMIC.

Conclusions: Among trials that enroll patients in HIC and LMIC/UMIC, authorship appears to be proportional to patient enrollment. This finding is limited by the fact that more than half of RCTs do not report enrollment by country. Moreover, there are important outliers as a significant proportion of RCTs had no authors from LMIC/UMIC despite enrolling patients in these countries. The findings in this study reflect a complex global RCT ecosystem that still underserves cancer control outside high-income settings.

KEYWORDS
authorship, clinical trials, global health, HICs, LMICs, oncology, patients enrollment, UMICs

INTRODUCTION

Over the past two decades, enrollment in oncology randomized controlled trials (RCTs) has become increasingly global in scope.[1–3] Although the vast majority of cancer RCTs are led and funded by investigators and sponsors in high–income countries (HIC), a substantial proportion of these will enroll patients in low–, middle–, and upper–middle–income countries (LMIC/UMIC).[1,4] Although this might benefit participating centers, patients, and researchers from LMIC/UMIC, their conduct has also raised several concerns, including; lack of consultation during trial design, differences in standard of care across regions due to limited drug access, limited slot allocation for LMICs that makes results interpretation difficult, post–trial access to medicines,[5] and proportionate recognition of investigators in subsequent publications.

Research parachutism occurs when investigators from one country use resources (academic, clinical, or societal) from another country without providing commensurate recognition and benefits in return.[6] One potential example of research parachutism is when investigators from HICs conduct studies in a low-resource setting without providing authorship to local investigators who were integral to the study conduct.[6]

In the current era, it is not uncommon to see 30 or more authors included on a manuscript of a large clinical trial.[7] Despite International Committee of Medical Journal Editors criteria for authorship, it remains unclear to what extent authorship on global RCTs reflects academic effort vs academic politics. There are concerns that fair distribution of authorship may not always occur in global health research partnerships when collaborators from LMIC and HIC work alongside each other.[8]

Despite the growing interest in global participation of oncology RCTs, to date, there are only a handful of reports on the allocation of authorship in LMIC/UMIC—and these are restricted to analyses of Sub-Saharan Africa.[9–11] To bridge this knowledge gap, we undertook the following study to understand (1) the allocation of authorship to investigators in LMIC/UMIC across all oncology RCTs conducted globally, and (2) the extent to which authorship was proportional to trial enrollment.

MATERIALS AND METHODS

Study design and search strategy

This study used an established database of all oncology RCTs conducted globally during 2014–2017.[12] RCTs were included if they were: a phase 3 study that involved any type of cancer and tested a cancer-directed therapy (systemic, radiation, or surgery). The current report represents a secondary analysis to understand the allocation of authorship among RCTs led by HIC that enrolled patients both in HIC and LMIC/UMIC. RCT leadership was defined based on the first author's institutional affiliation.

Data abstraction and outcomes

The study population was restricted to RCTs led by HIC, which enrolled participants from LMIC/UMIC. All eligible studies were reviewed using a standardized data abstraction form to capture information regarding authorship, journal of publication, funding, study design, statistical plan, and results. Data abstraction was performed independently by two members of the primary research team. The senior author (C.M.B.) periodically performed random duplicate abstraction to ensure data abstraction was of high quality. At the completion of data collection, 30 studies were randomly chosen for review; only 11 of 1020 variables (1%) were found to be discordant with the original assessment. Studies were classified into the country of origin based on the institutional affiliation of the first author; subsequent authors were also classified as being from HIC or LMIC/UMIC based on institutional affiliation. The country of origin was used to further divide studies into income level classifications based on the World Bank income classification.[13] There were no low-income countries.

For each RCT, we identified the proportion of authors from LMIC/UMIC. To explore whether the allocation of authorship is proportional to the level of participation, we undertook two comparative analyses. In the first, we compare the proportion of LMIC/UMIC authors listed in each published RCT article relative to the proportion of trial investigators that came from LMIC/UMIC. Trial investigators (i.e., physicians who enroll patients at the trial site) were identified from the Acknowledgments section and/or Appendices of published reports; each investigator was classified as coming from HIC versus LMIC/UMIC based on their country affiliation. In the second analysis, we explored the relationship between LMIC/UMIC authorship, and the number of patients recruited from LMIC/UMIC in each RCT. Patient enrollment was identified from Appendices of trial reports. For each RCT we classified the proportion of patients enrolled that came from HIC versus LMIC/UMIC.

Statistical analysis

Descriptive results (frequencies and percentages for categorical data, and medians and quartiles for continuous data) were generated using IBM SPSS (version 27.0 for Windows, Armonk, New York). Comparisons were made between groups of studies using χ^2 and Fisher exact

tests for categorical data, and the Mann-Whitney U for continuous data. We characterized trial differences between the two groups based on funding, types of cancers studied, types of experimental interventions, trial design, and outcomes. Associations between continuous variables were assessed by Spearman's correlation and visualized with scatterplots. p values less than 0.05 were considered significant; no adjustments for multiple comparisons were made.

RESULTS

Results of the search strategy

The global study cohort included 694 RCTs published during 2014–2017 (Figure 1); 636 (92%) were led by investigators from HIC. Among the 636 HIC-led trials, 186 (29%) enrolled patients in both HIC and LMIC/UMIC. Eighty-four RCTs (45%, 84 of 186) enrolled patients from a total of 11 LMICs, and 181 RCTs (97%, 181 of 186) enrolled patients from 26 UMICs; these groups formed the study cohort.

Characteristics of RCTs

The most common participating LMICs were India (50%, 42 of 84 LMIC trials), Ukraine (46%, 39 of 84), Philippines (27%, 23 of 84), and Egypt (14%, 12 of 84). The most common participating UMICs were Russian Federation (64%, 115 of 181), Brazil (52%, 94 of 181), Romania (34%, 62 of 181), China (31%, 56 of 181), Mexico (31%, 56 of 181), and South Africa (30%, 54 of 181).

Characteristics of the study cohort (n = 186) are presented in Table 1. The most common cancers studied were breast (20%, 38 of 186), hematologic (19%, 36 of 186), lung (15%, 28 of 186), gastrointestinal (13%, 25 of 186), and urologic (13%, 24 of 186). Compared to trials exclusively from HIC, trials that enrolled patients in HIC and LMIC/UMIC were more likely to evaluate therapies in the palliative setting (79% [148 of 186] vs. 59% [263 of 449], $p < .001$), test systemic therapies (96% [180 of 187] vs. 84% [376 of 449], $p < .001$) and be supported by industry (95% [177 of 186] vs. 65% [292 of 449], $p < .001$). Patient enrollment by country was available for 74 RCTs. The proportion of patients accrued from LMICs/UMICs varied substantially (Figure 1). In 50% (37 of 74) of trials, LMIC/UMICs contributed <15% of patients; a small proportion of LMIC/UMIC trials (10%, 8 of 74) contributed >50% of all patients in a given RCT.

Allocation of authorship and patient enrollment

Among the 186 RCTs led by HICs enrolling patients from LMIC/UMICs the median (interquartile range [IQR]) number of total authors was 19 (15, 23). The median (IQR) number of authors from LMIC/UMIC was 1 (0, 3); the median (IQR) proportion of authors from LMIC/UMIC was 6% (0, 16). Despite enrolling patients from LMIC/UMIC one-third (33%, 62 of 186) of RCTs had no authors from LMIC/UMIC, and one-quarter (27%, 51 of 186) had one author from LMIC/UMIC. There was no last author from LMIC and only 4% of last authors were from UMICs. The distribution of LMIC/UMIC authors is shown in Figure 2 and Figure S1.

Of the 186 RCTs that are led by HIC and enroll in LMICs/UMICs, half (51%, 95 of 186) reported the number of investigators by

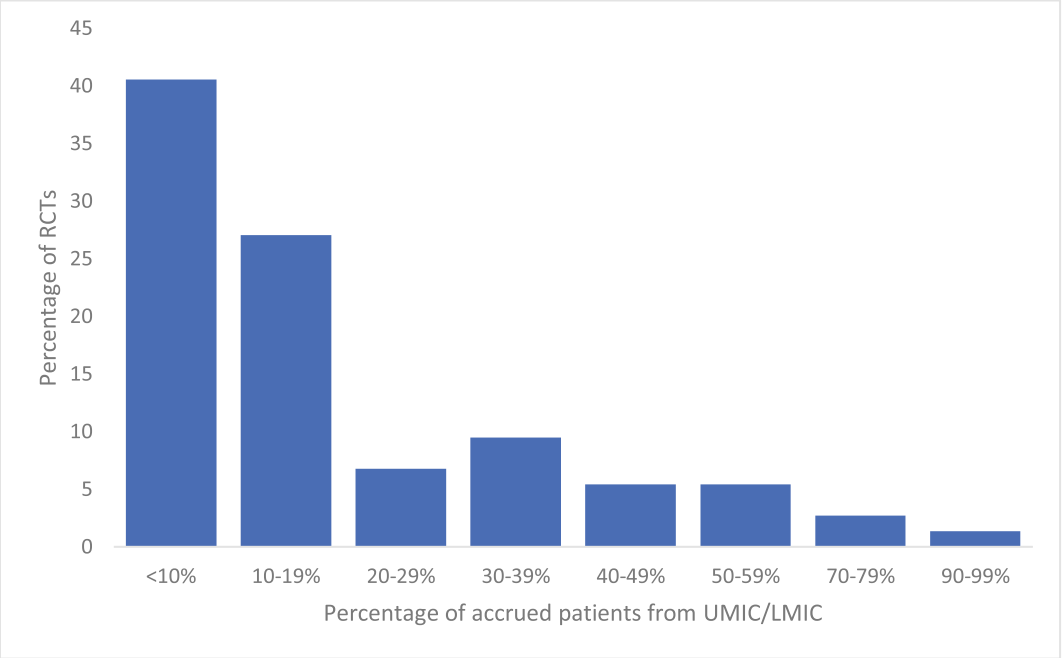

FIGURE 1 Proportional accrual by low- and upper middle-income countries that participate in oncology randomized controlled trials published globally 2014–2017 (n = 74).

TABLE 1 Characteristics of all oncology randomized controlled trials published globally 2014–2017 led by HIC that enrolled patients in LMIC/UMIC.

Characteristic	186 RCTs, No. (%)
Disease site	
Breast	38 (20)
Hematologic	36 (19)
Lung	28 (15)
Gastrointestinal	25 (13)
Urologic	24 (13)
Other	35 (18%)
Treatment intent[a]	
Palliative	147 (79)
Curative	5 (3)
Neoadjuvant/adjuvant	34 (18)
Experimental arm	
Systemic	180 (97)
Radiation/surgery	6 (3)
Control arm	
Active therapy	145 (78)
Placebo	32 (17)
Observation/BSC	9 (5)
Primary EP	
OS	66 (36)
DFS/EFS/RFS	24 (13)
PFS/TTF	74 (40)
Other	22 (12)
Industry funding	
Yes	177 (95)
No	9 (5)

Abbreviations: BSC, Best Supportive Care; DFS, Disease Free Survival; EFS, Event Free Survival; EP, End Points; HIC, high-income countries; LMIC/UMIC, low- and upper middle-income countries; OS, Overall Survival; PFS, Progression Free Survival; RCT, randomized controlled trial; RFS, Recurrence Free Survival; TTF, Time to Treatment Failure.

[a]Two were missing treatment intent.

country. The relationship between the proportion of investigators and the proportion of authorship is shown in Figure 3 and demonstrates a strong correlation (Spearman's ρ 0.637, $p < .001$ for both HIC with LMIC/UMIC and HIC alone). Forty percent (74 of 186) of RCTs reported patient enrollment by country; the relationship between the proportion of enrollment and proportion of authorship is even stronger than investigators as shown in Figure 4 (Spearman's ρ LMIC/UMIC 0.824, $p < .001$; HIC 0.823, $p < .001$). Among the 74 trials that report country enrollment, 34% (25 of 74) have no authors from LMIC/UMIC.

In an exploratory analysis, we evaluated the 25 of 74 RCTs that enrolled patients in LMIC/UMIC yet had no authors from LMIC/UMIC. In 20% of these RCTs (5 of 25), LMIC/UMIC patients represented a substantial proportion (>10%) of enrolled patients.

DISCUSSION

We have explored the allocation of authorship and patient enrollment among oncology RCTs that enroll patients in HIC and LMIC/UMIC. Several significant findings have emerged. First, 29% of HIC–led RCTs enrolled patients in LMIC/UMIC; one–third of these trials did not include any authors from LMIC/UMIC. Second, only 40% of RCTs report enrollment by country. Third, the allocation of authorship to LMIC/UMIC generally appears to be proportional to trial activity (i.e., the proportion of investigators and the proportion of enrolled patients). Fourth, there are important outliers to this finding, as a notable proportion of trials had no LMIC/UMIC authors despite having a substantial proportion of patients enrolled from LMIC/UMIC. Finally, it is notable that in most trials, only a very small proportion of total patient accrual comes from LMIC/UMIC.

It is worth considering our findings in light of existing literature. A recent bibliometric analysis on authorship among research conducted in Sub-Saharan Africa found that 15% of studies had no authors affiliated with the LMIC in which the study took place.[14] Similar rates of authorship parachutism have been reported in infectious disease and pediatric research publications.[15,16] A recent review of articles about corona virus disease 2019 with African content reported that only 34% had an African author.[17] Findings of a cross-sectional review of articles published by the *Journal of Global Oncology* showed continued underrepresentation of investigators from Sub-Saharan Africa; among articles with African content only 45% of first authors and 41% of last authors were African.[9] Wong et al.[18] described authorship among 454 oncology RCTs published during 1998–2008. Only 19% (87 of 454) included authors from LMIC/UMIC; only 17% of these had LMIC/UMIC investigators as first or corresponding authors. Forty RCTs (9%) were conducted in HIC and LMIC/UMIC; 25% of which had no authors from LMIC/UMIC. In alignment with our findings, Wong et al.[18] noted the increasing publications of industry funded global RCTs, with lack of leadership role granted to investigators from investigators from LMICs.

Given the lack of alternative funding sources, it is not surprising that research in LMIC/UMICs is heavily reliant on industry funding. This limits the degree to which research priorities within the specific health system are addressed. Increasing globalization of RCTs is often touted as an opportunity to learn more about treatment efficacy in populations that are often underrepresented in clinical trials. Although this is a laudable goal—the reality is that so few patients are accrued from any given LMIC/UMIC region that it is unlikely to provide useful information in this regard.

An unexpected finding from our study is that the relationship between proportion of authors and proportion of enrollment is comparable between LMIC/UMIC investigators and HIC investigators (i.e.,

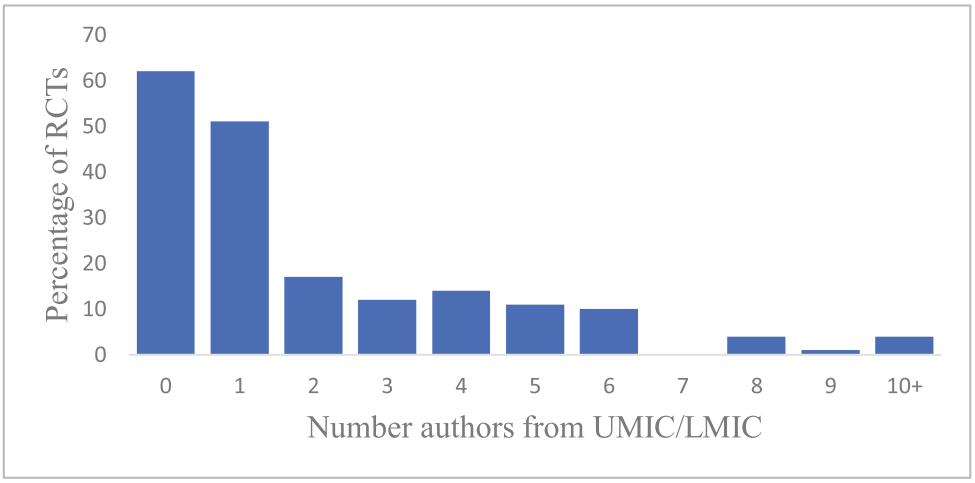

FIGURE 2 Distribution of authors among oncology randomized controlled trials published globally 2014–2017 led by high-income countries that enrolled patients in low- and upper middle-income countries (n = 186).

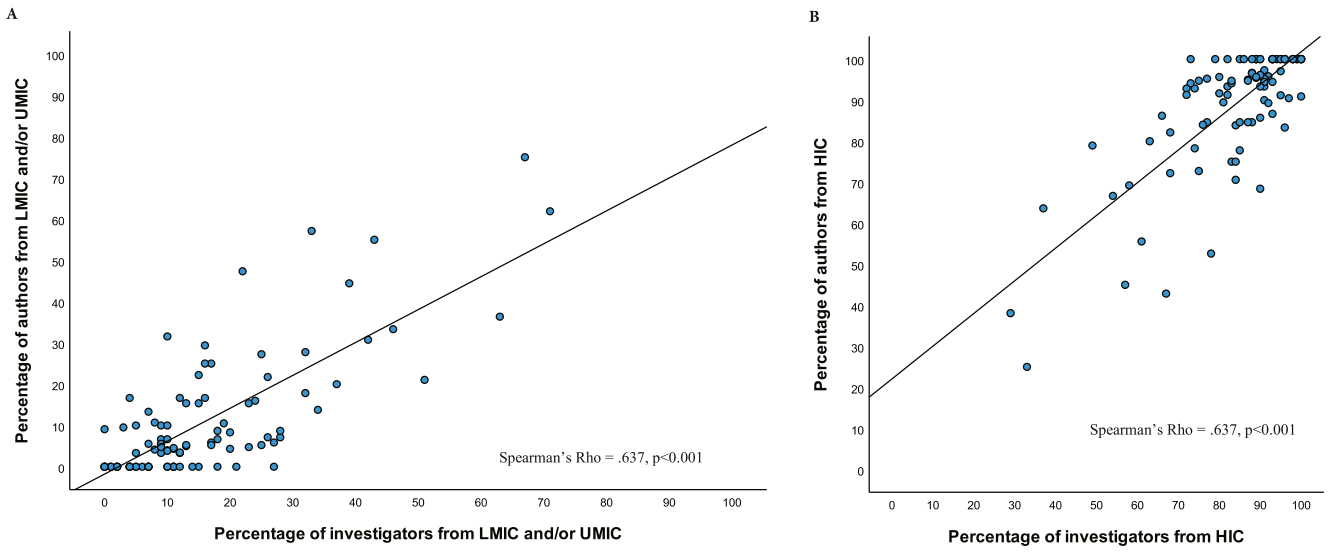

FIGURE 3 The relationship between proportion of investigators and proportion of authors from low- and upper middle-income countries (LMIC/UMIC) (A) and high-income countries (HIC) (B) among all oncology randomized controlled trials published globally 2014–2017 led by HIC that enrolled patients in LMIC/UMIC (n = 95).

although there are far fewer LMIC/UMIC authors, it is generally proportional to active study enrollment). Our finding that middle authorship is proportional to trial enrollment is consistent with the practice of most industry trials in awarding authorship based on specific accrual metrics. This contrasts with a study by Hoekman and colleagues[19] who reported that authorship rates per enrollment were far lower for LMIC investigators than HIC investigators; this analysis included RCTs published in 2005–2011. Whether our conflicting results represent a temporal improvement in authorship allocation is unclear. Within our own study, it is notable that there are outlier trials with little to no representation of authors from LMIC. Moreover, because less than half of RCTs in our study report enrollment by country, our results may not be generalizable to all oncology trials. It is possible that the RCTs that do not list enrollment by country allocate authorship less equitably.

There are many reasons why patients from LMIC/UMIC may be underrepresented in oncology RCTs and why most RCTs are led by investigators in HICs. First, most researchers from LMIC/UMIC have substantially larger clinical workloads without any paid protected time for research and lack supporting infrastructure.[20] Second, formal training in research methodology is not emphasized in many medical schools and postgraduate training programs; this limits research capacity as trainees move into faculty positions. Third, the language of cancer research, based on Western medical tradition and the English language, pose barriers to the many LMIC/UMIC researchers. Countries that use their native language in research and publish in reputable local journals are likely to overcome this language barrier yet not be internationally recognized for their work. Fourth, regulatory approvals required to initiate clinical

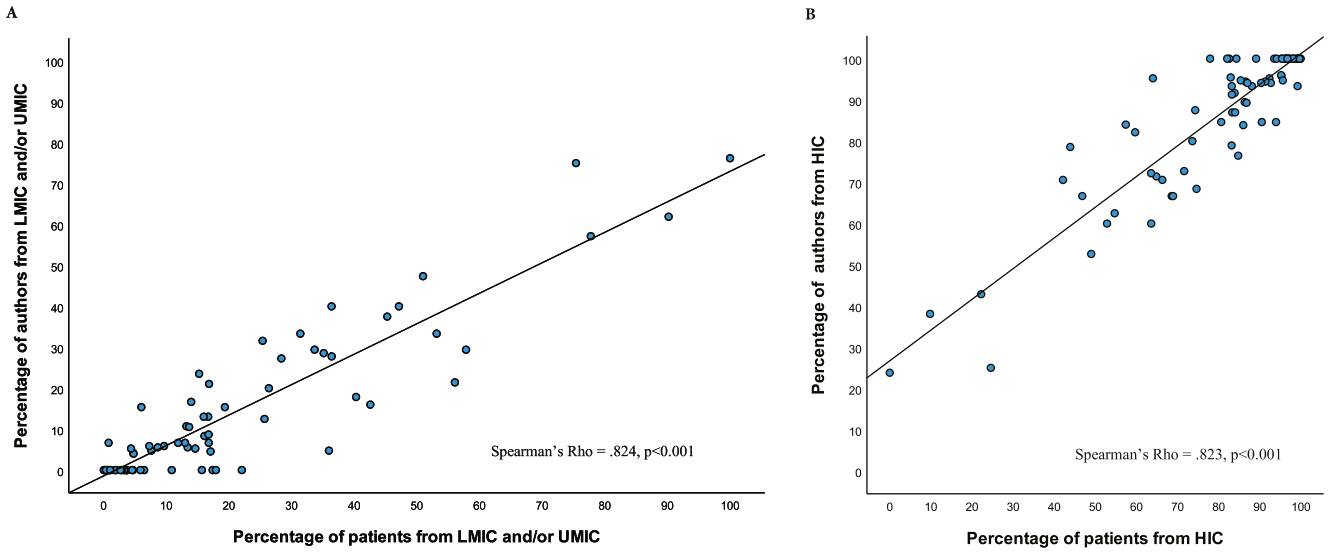

FIGURE 4 The relationship between proportion of patient enrollment and proportion of authors from low- and upper middle-income countries (LMIC/UMIC) (A) and high-income countries (HIC) (B) among all oncology randomized controlled trials published globally 2014–2017 led by HIC that enrolled patients in LMIC/UMIC (n = 74).

TABLE 2 Recommended policy action to improve participation of LMIC/UMIC in oncology RCTs.

1.	Principal investigators from HIC and pharmaceutical industry sponsors should actively engage colleagues in LMIC/UMIC in global RCTs to ensure that centers in these countries are supported to make a meaningful contribution to patient accrual.
2	Regulatory bodies and health systems in LMIC/UMIC should mandate co-creation of research agenda and trial design and that participation will improve country-level research capacity.
3	LMIC/UMIC medical schools and postgraduate training programs should incorporate research methods into teaching curricula and foster a culture that promotes active investigation.
4	LMIC/UMIC government agencies and civil society need to invest in cancer research. This includes provision of funds for "home-grown" research and also requires faculty positions that facilitate clinical work AND active research.
5	CONSORT and journal editors should mandate that manuscripts of global RCTs report country-level accrual.

Abbreviations: CONSORT, Consolidated Standards of Reporting Trials; HIC, high-income countries; LMIC/UMIC, low- and upper middle-income countries; RCTs, randomized controlled trials.

trials in many LMIC/UMIC are cumbersome and very slow; this inhibits the ability to join trials early and/or lead in-house studies. Fifth, the research agenda is largely controlled by investigators in HICs who have access to funds from the pharmaceutical industry.[12] LMIC investigators are typically invited in the later stage of the trials mostly to boost enrollment, this lack of coproduction of the research agenda impacts the designation of leadership roles and limits country-specific capacity building. The lack of national financial resources in most LMIC/UMIC perpetuates structural inequities in the global research ecosystem. Finally, based on experience from several of members of our research team, an unspoken reason why LMIC/UMIC investigators are not offered leadership roles relates to entrenched beliefs that LMIC/UMIC are not capable of leading clinical trials. These structural and systemic biases need to change if the oncology community is serious about generating evidence that can change cancer care and outcomes for patients worldwide. Recent data also suggest that investigators in HICs have much to learn from investigators in LMIC/UMIC where oncology RCTs are more likely to identify new and meaningful treatment advances for patients.[12]

Our results have policy implications (Table 2). First, there needs to be a fundamental shift in how leaders in HIC trials conceptualize global RCTs involving LMIC/UMIC. Although the current study demonstrates that authorship is proportional to trial activity, it is a notable failure of the current system that most global trials (50%) enroll very few patients (<15%) from LMIC/UMIC. Second, within LMIC/UMIC, regulatory bodies and health systems should expect and mandate co-creation of the research agenda and study design.

Trial co-leadership and data co-ownership should be discussed before starting these collaborative trials and included in the contract. Institutional review boards should not succumb to industry or external investigator pressure to open trials that will not benefit local populations. Participating institutions should make sure that any research done empowers the country's research capabilities in general, enabling local researchers to formulate their questions. Third, training institutions and relevant bodies should initiate research training early in oncology education, encourage the "clinical research mindset" and prepare for in-service capacity building. Fourth, the government and civil society should mobilize funds for cancer research that will address issues relevant to their specific health system and led by their own oncologists. Governments must minimize the risk of brain drain by creating an appealing environment to research through job creation and career development opportunities. Fifth, Consolidated Standards of Reporting Trials (CONSORT) and journal editors should mandate authors of RCTs to report patient enrollment by country; this will provide better transparency for academic credit and allow clinicians to understand how the results may (or may not) apply to patients in their own clinical practice.

Our results should be interpreted considering methodological limitations. Our cohort of RCTs only included English articles and journals, this omits a range of non-English non-PubMed indexed journals publishing national literature (e.g., Latin America, China, and Russia). The analysis grouped countries into economic regions, but we recognize that LMIC/UMIC is a heterogeneous group, LMIC might not share similar challenges as UMIC, and we also acknowledge that the country's research leadership and capacity differ even within one economic block. RCTs included in our study were published up to 2017, and thus, potentially not representative of the current authorship practice as the increasing number of immune-oncology trials have been published after that; a cross-sectional study has shown that immunotherapy RCTs in oncology have become more global, as they enroll patients from across the globe.[21] To understand whether authorship is allocated proportionally to trial contributions, we used the number of LMIC/UMIC investigators and number of LMIC/UMIC patients enrolled. It was notable that the strength of association between enrollment and authorship was very high (Spearman's ρ, 0.82). In a sensitivity analysis, we found good correlation between the number of investigators and the number of patients enrolled (Figure 2). However, these measurements remain imperfect surrogates for trial contributions; mere recruitment of patients on trials is not an appropriate measure of contributing to the overall study. Moreover, these specific metrics were not reported by more than half of RCTs. This quality of reporting issue has broader implications for how clinicians may apply the study results to their own clinical practice. It also raises the possibility that our results have under or overestimated inequity in allocation of authorship (i.e., if trials that do not report enrollment by country are also less or more equitable in how they allocate authorship). Finally, although it would have been useful to distinguish trials sponsored by industry from those that only receive funding, this level of granularity was not captured in the study data set and is therefore not available for analysis.

In summary, among trials that enroll patients in HIC and LMIC/UMIC, authorship is proportional to patient enrollment. However, there are important outliers as a significant proportion of RCTs had zero authors from LMIC/UMIC despite enrolling patients in these countries. Moreover, this analysis was limited by the fact that more than half of RCTs do not report enrollment by country. Journal editors and CONSORT should mandate RCT reporting of patient enrollment by country. Our results also demonstrate that in most global RCTs, very few patients from LMIC/UMIC are enrolled. Reasons for this are not understood but need to be addressed if the oncology community is serious about promoting research that can change practice and outcomes worldwide. In an era where diversity is encouraged, and as we encourage equitable collaboration and authorship allocation, leaders of oncology trials should ensure that investigators from LMICs/UMICs are engaged as true partners in each step of the research enterprise; it would be a step backward if LMIC/UMIC investigators are granted honorary authorship without meaningful engagement. With growing research capacity, investigators in LMIC/UMIC should be increasingly engaged not only in patient enrollment, but also in the research enterprise including trial design, analysis, manuscript drafting, and presentation of results. This level of engagement will generate research that is more meaningful for diverse health systems; it will also allow the next generation of LMIC/UMIC investigators to develop skills and experience to eventually lead RCTs that address priority question in their own health systems (Figure S2).

AUTHOR CONTRIBUTIONS

Fidel Rubagumya: Concept and design, acquisition, analysis, or interpretation of data, drafting of the manuscript, critical revision of the manuscript, and content guarantor. **Adam Fundytus:** Concept and design and critical revision of the manuscript. **Sophie Keith-Brown:** Acquisition, analysis, or interpretation of data and critical revision of the manuscript. **Wilma M. Hopman:** Acquisition, analysis, or interpretation of data, statistical analysis, critical revision of the manuscript, and content guarantor. **Bishal Gyawali:** Critical revision of the manuscript. **Deborah Mukherj:** Critical revision of the manuscript. **Nazik Hammad:** Critical revision of the manuscript. **CS Pramesh:** Critical revision of the manuscript. **Ajay Aggarwal:** Critical revision of the manuscript. **Alexandru Eniu:** Critical revision of the manuscript. **Manju Sengar:** Critical revision of the manuscript. **Rachel S. R. Riechelmann:** Critical revision of the manuscript. **Richard Sullivan:** Critical revision of the manuscript. **Christopher Booth:** Concept and design and critical revision of the manuscript, critical revision of the manuscript, and content guarantor.

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CONFLICT OF INTEREST STATEMENT

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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