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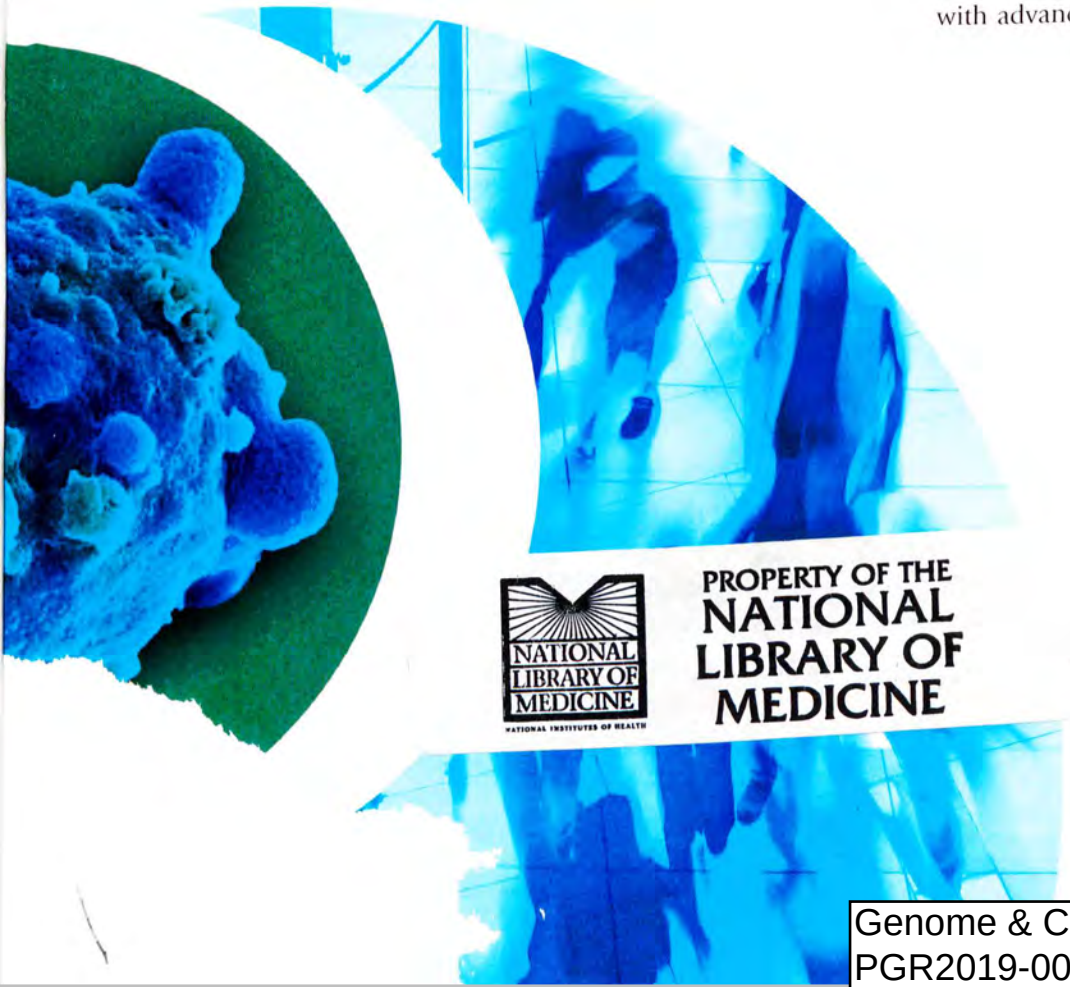

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Reasons given by patients for participating, or not, in Phase 1 cancer trials

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ABSTRACT

Background: Communication with patients contemplating Phase 1 cancer trial participation can be challenging. Controversy exists as to whether they are provided with sufficient information to give genuinely informed consent. We present data examining the reasons patients gave for trial entry.

Method: Following discussions with oncologists about Phase1 trials, participants completed a 19-item study specific 'accept or decline measure' exploring hope, expectations of benefit, altruism, concerns, and general perceptions of the trial information. They also completed 2 standardised questionnaires measuring psychological morbidity and predisposition towards optimism.

Results: Forty patients completed the study questionnaires. Patients were generally optimistic with few concerns about the experimental nature of Phase 1 trials. Most 36/40 (90%) consented to trial entry. Fifty-one percent thought the trial was the only treatment option available. The four main reasons for trial entry were: expectation of some medical benefit (21%); trial the best available option (21%); to maintain hope (15%) and to help with research (13%). Only one patient gave altruism as their main reason for trial participation.

Conclusion Patients considering Phase 1 trials may be a self-selected group with optimistic expectations of personal benefit driving trial entry rather than altruism. Achieving genuinely informed consent and avoidance of therapeutic misconceptions in such patients may be difficult.

1. Introduction

Phase 1 (P1) clinical trials are crucial in the development of new anti-cancer treatments. New agents that have shown promise in the laboratory are usually tested in patients with advanced disease. The aims of P1 trials are to determine safe dosage range and identify side-effects. These trials convey small prospects of therapeutic benefit and carry varying possibilities of side-effects.[1] It is therefore not surprising that recruiting patients into these studies generates ethical debate[2] and creates challenging communication issues.[3,4]

A systematic review by Todd and colleagues[5] examined the positive and negative attitudes of patients with advanced cancer towards research. In this review 11 studies were identified for evaluation. Most involved hypothetical scenarios and only two were with patients in P1 trials – one qualitative[6] and one quantitative.[7] Common motives for participation were altruism, hope, and for personal benefit. Concerns about negative impact on symptoms and risk of increased hospital admissions emerged as reasons for declining participation. Most patients were positive in general about research despite having advanced disease. Conclusions were that more

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