Characteristics and Reporting of Seamless Early-Phase Trials in Oncology – A Cross-Sectional Analysis of Trials Registered on ClinicalTrials.gov

REMEDY
Research Ethics in Medicine Study Group

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Background

Seamless trials often combine two distinct phases of drug development, allowing for the concurrent assessment of objectives traditionally addressed in separate trials. This is a possible way to accelerate drug development [1, 2].

The growing importance of seamless trials can be seen in oncology research, especially in the early stages of drug development. Clinical trial registries, such as the ClinicalTrials.gov database, should keep pace with evolving clinical trial models to ensure a comprehensive and accurate representation of trial characteristics and results.

Objectives

Our aims are:

1) examine the basic characteristics of seamless early-phase oncology trials registered on the ClinicalTrials.gov registry.

2) determine results reporting rates and identify factors associated with results reporting.

Methods

We define seamless early-phase trials as Phase 1/2 trials or Phase 1 trials with planned expansion cohort(s) [3]. The method overview is presented in Figure 1.

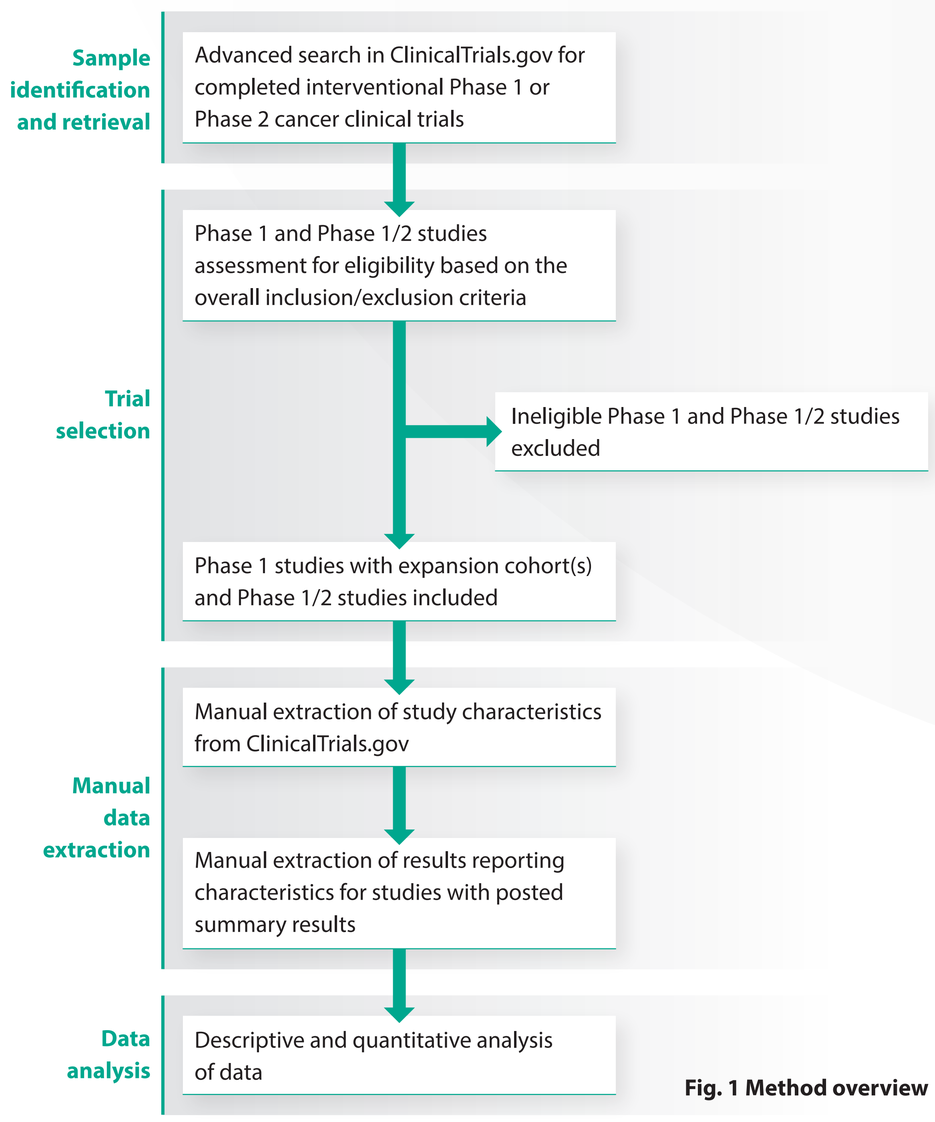

Fig. 1 Method overview

Results

We analysed 1051 early-phase seamless oncology trials completed between 2016 and 2020 (see Figure 2).

Characteristic	All trials, N (%)
Number of trials	**1051** (100%)
Phase	
Phase 1	**562** (53.5%)
Phase 1/2	**489** (46.5%)
Enrolled participants	
1-50	**594** (56.5%)
>51	**457** (43.5%)
Funder type	
Industry	**596** (56.7%)
Non-industry	**238** (22.6%)
Partially-industry	**217** (20.6%)
Study population age	
Adults	**987** (93.9%)
Pediatric	**3** (0.3%)
Both	**61** (5.8%)
Type of intervention	
Targeted therapy	**263** (25.0%)
Immunotherapy	**238** (22.6%)
Cytotoxic therapy	**67** (6.4%)
Other	**25** (2.4%)
Mixed	**458** (43.6%)
Number of drugs evaluated	
Multiple agents	**654** (62.2%)
Single agent	**397** (37.8%)
Type of cancer	
Solid	**752** (71.6%)
Hematological	**250** (23.8%)
Both	**46** (4.4%)
Not reported	**3** (0.3%)
Number of trial's sites	
Multi-site	**733** (69.7%)
Single-site	**307** (29.2%)
Not reported	**11** (1.0%)
Recruitment regions	
United States (US)	**476** (45.3%)
Non-US	**298** (28.4%)
Multicenter incl. US	**266** (25.3%)
Not reported	**11** (1.0%)

Fig. 2 Characteristics of clinical trials

We found that only **365** of **1051** trials (34.7%) reported results on the ClinicalTrials.gov. The results reporting rates for 24 months was **24.0%**. The overall reporting rate for Phase 1/2 studies was more than three times higher than for seamless Phase 1 studies.

Our analysis revealed an additional problem

Study characteristics and results reports on ClinicalTrials.gov are often available for the entire trial, rather than for specific stages of a seamless trial. This causes difficulty in accurately tracing the trial process.

Conclusion

Our study provides cross-sectional data on seamless early-phase oncology trials registered on the ClinicalTrials.gov registry. In addition, we found that ClinicalTrials.gov should be optimized to enable easy tracking of the entire trial process and to accommodate the complexity of seamless trial design.

References

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Questions? Ask me

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Scan to view the study protocol