The treatment agents in trials were varied, with more than 50 different agents included in the registry in 2007-2010. As shown in Table 1, less than one-third of trials were FDA-approved, and 10% of trials were Phase III or IV, regardless of the approval status of the study agent(s).

Methods

- A dataset comprising 96,346 clinical trials was downloaded from ClinicalTrials.gov on September 27, 2010, in XML format and a database for the Aggregate Analysis of ClinicalTrials.gov (AACAT) was created to facilitate analysis.
- A subset of trials was identified, corresponding to the FDA's enrollment mandate of registration in 2007.
- A process was developed to annotate and validate disease conditions in order to create a comprehensive database.
- A combination of National Library of Medicine (NLM) MeSH terms and additional non-MeSH (free-text) terms were annotated by disease, resulting in a summary algorithm used to classify trials as depicted in Figure 1.
- Trials identified as "oncology" were then further categorized into cancer types.
- The characteristics of trials identified as RCC-specific were further analyzed.

Results

- Of 670,070 interventional studies registered between October 2007 and September 2010, 89,422 (13%) focused on oncology, the highest among all specialties represented.
- 108 RCC trials studied treatment agents (which were identified and initiated in the defined timeframe).
- 43% assessed agents included in the NCCN RCC Guidelines at the time of study initiation and 18% studied FDA-approved treatments that were not included in the guidelines. 34% of trials included a novel agent.
- As shown in Table 1, less than one-third of trials were randomized, blinded, multi-arm, or multi-site (Phase III or IV), regardless of the approval status of the study agent(s). 60% of studies were industry sponsored and <1% included overall survival as a primary endpoint.
- Across all RCC trials from 2007-2010, 50% are randomized, 24% recruiting, 13% withdrawn/terminated, 13% unknown, and 11% complete.

Conclusions

- The findings identify strengths and weaknesses in trial design, patient populations, and evidentiary development that need to be carefully considered in an era of increasing focus on drug development and comparative effectiveness research.
- The majority of new studies and accrual in RCC were not randomized, blinded, multi-arm, or multi-site (Phase III or IV), regardless of the approval status of the study agent(s). 60% of studies were industry sponsored and <1% included overall survival as a primary endpoint.
- Across all RCC trials from 2007-2010, 50% are randomized, 24% recruiting, 13% withdrawn/terminated, 13% unknown, and 11% complete.

The ClinicalTrials.gov database provides a unique opportunity to understand the breadth of the interventional trials in oncology.

Optimizing clinical research includes increasing studies of novel therapeutics and improving the comparative effectiveness research portfolio by increasing utilization of pragmatic designs, registries and late-phase trials.

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