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Availability of results of academic randomized trials involving cooperative groups in oncology in France: A systematic search of clinical trial registries

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ABSTRACT

Background: Cooperative groups' involvement is increasing in academic oncological research. We aimed to assess the impact of sponsoring by cooperative groups in France on the availability of results of academic randomized trials in oncology.

Methods: We performed a systematic search using ClinicalTrials.gov and the European Clinical Trials Register. We searched for all academic randomized trials in oncology conducted in France between January 1, 2005 and January 1, 2015. The inclusion criteria were: completed or terminated, phase 2 or 3 randomized trials with an academic (non-industry) sponsor. The main outcome was the publication of the results of trial (either as a journal article or as posting results in a registry) across each type of sponsor.

Results: We included 211 randomized trials, mainly phase 3 (n = 135, 64%) and evaluating pharmacological treatments (n = 149, 71%). French cooperative groups were involved in 69 trials (33%), as part of a collaboration in one third (n = 23) of instances. Seventy-one (34%) trials were run by oncologic hospitals, 50 (23%) by university hospitals, and 21 (10%) by European organizations. Seventy-seven randomized trials (36%) had available results (published n = 73, posted n = 6). Cooperative groups were involved in half of those that have been published (37/73). The cumulative probability of results availability was 57% for cooperative groups, 41% for European organizations, 32% for oncologic hospitals, and 17% for university hospital at 10 years from the beginning of trials (p = 0.0006). In the case of collaboration with cooperative groups, the cumulative probability of results availability achieved 59% for university hospitals and 74% for oncologic hospitals.

Conclusion: The availability of results of randomized trials in oncology remains limited and almost exclusively through publications, but is higher when cooperative groups are involved.

Policy summary: Sponsoring by a cooperative group should become the rule in academic trials to increase availability of trial results.

1. Introduction

Randomized controlled trials are the gold standard to evaluate therapeutic interventions and provide the most reliable evidence on the efficacy and safety of healthcare interventions [1]. In oncology, they have led to significant advances in cancer treatment in recent decades [2]. These trials are mainly funded and performed by pharmaceutical companies for the specific purpose of drug registration and approval. Academic trials are also conducted, to improve the standard of care for cancer patients, for instance by evaluating treatment combinations with drugs from different companies, or by running trials in a specific population or non-pharmacological trials evaluating surgery or radiotherapy.

In the late 1950 s, the National Cancer Institute (NCI) first established a system of cooperative groups to perform multi-institutional oncology trials [3]. These cooperative groups are not-for-profit organizations consisting of networks of researchers who develop and conduct cancer clinical trials. Usually acting as study sponsor and benefiting from their own operational resources, they have a strong track record of designing and completing trials. Cooperative groups have since been set

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up in all countries [4–7]. They currently serve as models for cancer clinical trials throughout the world [3,8]. For instance, the treatment of non-small cell lung cancer and other thoracic malignancies has greatly benefited from the efforts of cooperative groups worldwide [7] and cooperative groups have been involved in 30% of trials evaluating breast cancer therapies [9].

In France, as in many other countries, academic research is conducted by university hospitals (i.e. multidisciplinary hospitals), oncological hospitals, or cooperative groups. Ten organ specific cancer cooperative groups who are used to conducting and sponsoring clinical trials have joined together to form a French network of cooperative groups called "cooperative groups in oncology" (GCO). They have signed an ethical charter that defines their relationship with industry and they are approved by the French NCI (INCa) (Details in Supplemental Text 1) [5].

The role of sponsors is not only to promote trials, but also to ensure that they run smoothly and to provide access to their results [10]. Underreporting of trial results has been increasingly recognized over the past decade as the main cause of wasted medical research [11–13]. Timely dissemination of clinical trial results is required to honor the commitment of study participants, advance the research enterprise, and improve clinical care [14]. Dissemination is principally achieved through publication in peer reviewed biomedical journals, and less through reporting of results on clinical trial registries as now required by many authorities [15–17].

Compliance with clinical trial reporting remains poor [18,19], and between 25% and 50% of clinical trials remain unpublished [20,21]. For example, in oncology, among 598 completed randomized trials registered on ClinicalTrials.gov between 2008 and 2012, 398 (66.6%) had been published and trials funded by academic institutions were less likely to be published than NIH-funded trials (adjusted odds ratio, 0.48; 95% CI, 0.25–0.96) [22]. However, another study assessing trials performed at the Memorial Sloan Kettering Cancer Center found no overall difference in the probability of publication based on the type of sponsor (industry, national cooperative groups and institutional) [23]. Whether there is a difference in the availability of results from randomized trials in oncology by the type of academic sponsor remains unclear, as well as the impact of cooperative group involvement.

Our aim was to assess the proportion of phase 2 and 3 academic randomized trials in oncology involving cooperative groups and the availability of their results (i.e., posted on registries or published) compared to other academic sponsors using ClinicalTrials.gov and European Clinical Trials Register (EU-CTR), taking the example of France over a ten year period (2005–2015).

2. Methods

2.1. Search strategy and selection of trials

We performed a search on ClinicalTrials.gov in order to identify all phase 2 and 3 randomized trials in oncology performed in France between the first of January 2005 and the first of January 2015, using the following keywords: (cancer or tumor | Neoplasms | France | Phase 2, 3 | Start date from 01/01/2005–01/01/2015). This search was performed on June 5th, 2019. We then applied the following inclusion criteria: completed or terminated trials, phase 2 or 3 randomized trials, trials with an academic (non-industry) sponsor. As the trial status is not always updated, we also checked if " Active, not recruiting " and " recruiting " trials had posted results or a publication; if it was the case, we included them.

We performed the same search in EU-CTR (https://www.clinicaltrialsregister.eu/ctr-search/search) in order to identify additional trials not already included.

2.2. Identification of academic sponsor

We classified each trial according to the type of sponsor. We considered four categories of sponsor: 1) French cooperative groups (Supplemental Text 1), 2) university hospitals, 3) oncologic hospitals and 4) European organizations (e.g., European Organisation for Research and Treatment of Cancer (EORTC)). The cooperative group could be involved alone in the trial, or associated with another partner. To identify any collaboration with cooperative groups, we checked the responsible parties listed in the trial registries and the sponsors mentioned in publications.

We then divided the French cooperative groups in two sub-groups: those pertaining to the GCO network (List in Supplemental Text 1) and those not part of that network.

2.3. Assessment of public availability of trial results

For each identified trial, we assessed whether results for the primary outcome was publicly available. We searched first whether results were posted on ClinicalTrials.gov, and then whether the trial had been published.

Two authors (PC, BM) screened independently publications of each trial mentioned on ClinicalTrials.gov either in the item " Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number) " or in the item " Publications of results " completed by the trial investigators in order to identify the publication presenting the results of the primary outcome. Disagreements were discussed to achieve consensus. When results were available, we collected the date the study results were posted on the registry and/or the date of publication in a journal. In case of a trial that was both published and with posted results, we took into account the earlier date.

2.4. Data extraction

We extracted from ClinicalTrials.gov: the NCT number, the trial status, the phase, the condition, the interventions, the outcome measures, the sponsors/collaborators, and the start date. For each identified published trial, two authors (PC, BM) extracted independently the journal title, the year of publication, the number of randomized patients, the 2 year impact factor at the date of publication using Clarivate Analytics, and if the publication reported favorable results for the primary outcome or not based on their statistical significance.

2.5. Statistical analysis

Quantitative variables were described with median (quartile 1–3, IQR) and qualitative variables with number and percentages. We used the Kaplan-Meier method to describe the cumulative probability of results availability over time for each of the four academic sponsors. All trials without available results were censored on October 4th, 2019. We used a Kruskal-Wallis test to compare the impact factor of journals and time to publication of published trials. We used Fischer Exact test to compare frequency of results posting on clinicaltrials.gov. A 2-sided P value of less than 0.05 was used for statistical significance.

All data were analyzed with R V.3.3 (R Core Team, Vienna, Austria) [24].

3. Results

3.1. Selection and Characteristics of trials

The flow chart of trials selection is in Fig. 1. The electronic search of ClinicalTrials.gov yielded 1924 studies. Among the 1367 completed or terminated studies, we identified 202 eligible randomized trials. The electronic search of EU-CTR reported 515 studies among which we identified 3 additional trials. Adding the 6 terminated trials with a link

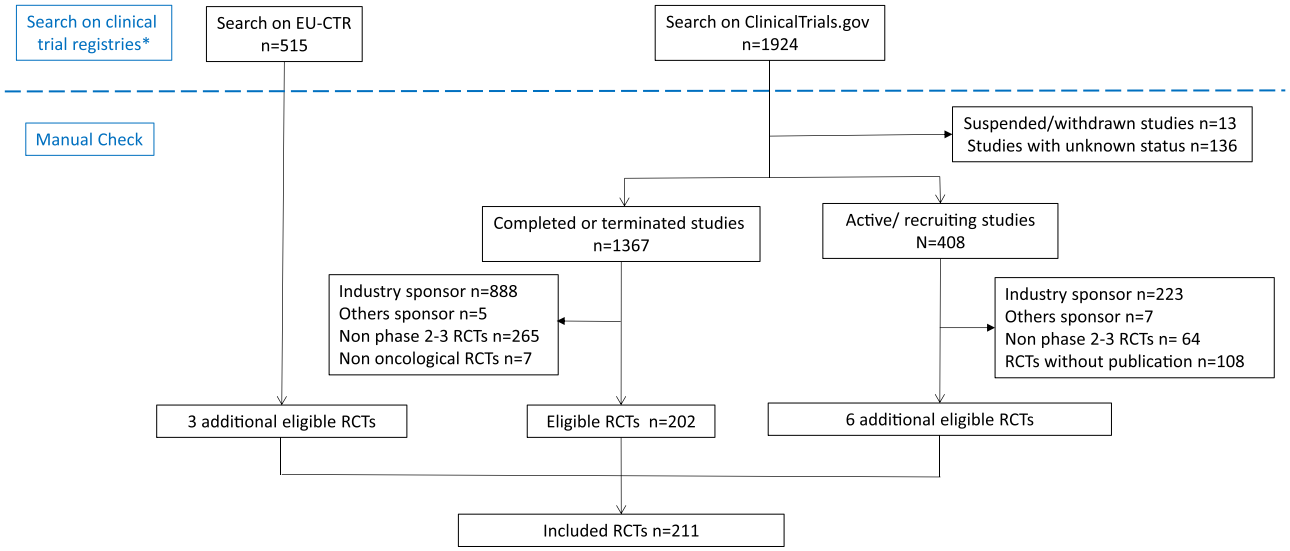

Fig. 1. Flow chart of selection of trials.

to the publication falsely referenced "Active/ recruiting" on the website, we finally included 211 randomized trials.

The characteristics of included trials are presented in Table 1. The majority of trials were pharmacological trials (n = 149, 71%) and phase 3 (n = 135, 64%). The four most frequent cancers studied were breast, digestive, hematology and lung. One third of trials (n = 57) concerned a surgical stage of the disease and 47% (n = 83) advanced and metastatic disease. Around two thirds of outcomes (n = 133) were classic outcomes in oncology (event free survival, response, overall survival and progression) and only 12% (n = 24) referred to toxicity or patient outcome reporting.

Table 1
Characteristics of the 211 included randomized trials.

Trial characteristics	Number (%)
Phase 2	76 (36)
Phase 2–3	14 (7)
Phase 3	121 (57)
Pharmacological trial	149 (71)
Non pharmacological trial	62 (29)
Trials assessing radiotherapy	14 (23)
Trials assessing surgery	8 (13)
Trials assessing strategy	6 (9)
Other	34 (55)
Type of cancer	42 (20)
Breast	42 (20)
Digestive	33 (16)
Hematology	22 (10)
Lung	12 (6)
Hepatology	12 (6)
ORL	12 (6)
Urology	9 (4)
Neurology	9 (4)
Soft tissue sarcoma	7 (3)
Gynecology	8 (4)
Multiple cancers	3 (1)
Dermatology	
Stage of disease (except hematology, n = 178)	57 (32)
Surgical	19 (10)
Locally advanced	27 (15)
Advanced	51 (29)
Metastatic	5 (3)
Palliative	9 (5)
Screening/diagnostic	3 (2)
All stages	7 (4)
Not provided	
Primary outcomes	67 (32)
Event free survival	30 (14)
Response	23 (11)
Overall survival	13 (6)
Progression	16 (8)
Patient outcome reported	8 (4)
Toxicity	54 (25)
Other	

3.2. Identification of academic sponsor

French cooperative groups were involved in 69 trials (33%), as part of a collaboration in one third (n = 23) of instances (13 (6.2%) with university hospitals, 7 (3.3%) with oncologic hospitals and 3 (1.4%) with European organizations). Oncologic hospitals performed 71 trials (34%), university hospitals 50 trials (23%) and European organizations 21 (10%) (Fig. 2, left part). Of the trials that involved cooperative groups without collaboration (n = 46), 34 trials (74%) were performed by GCO members and 12 (26%) by non-GCO members.

3.3. Trials characteristics according to academic sponsor category

The two major topics of academic trials of university hospitals were digestive and hepatic cancers (n = 20, 40%). For cooperative groups, it was hematology and lung cancer (n = 37, 53.6%), for oncologic hospitals breast and digestive cancers (n = 44, 61.9%) and for European organizations urologic and neurologic cancers (n = 8, 38%) (Supplemental Table 1). Oncologic hospitals performed the most phase 2 trials (n = 36, 50.7%). University hospitals focused their trials on surgical and locally advanced stages (n = 21, 48.9%) whereas cooperative group trials focused on advanced and metastatic stages (n = 29, 64.4%). Oncologic hospitals trials were equitably distributed between these two stages. University hospitals performed the most non pharmacological trials (n = 24, 48%). Oncologic hospitals trials were most likely to report a patient reported outcome and toxicity as a primary outcome (n = 14, 19.7%).

3.4. Public availability of trial results

Seventy seven trials (36%) had publicly available results. The median follow-up period was 9 years (IQR 7–11) from the trial start date. We identified 73 publications for 211 trials (35%) (List in Supplemental Text 2). Only six trials (3%) had posted results on a clinical trial registry (5 in ClinicalTrials.gov. and 1 in EU-CTR). Two trials had posted results and a publication; the first available of the two was the publication. Therefore, results of 64% of randomized trials were still missing

Fig. 2. Distribution of randomized trials performed according to academic sponsor and their related publications,Detail of collaboration with cooperative groups: for university hospitals 9 published trials over 13 (69%), for oncologic hospitals 4/7 (57%) and for European organizations 1/3 (33%).

(n = 134).

The median number of randomized patients was 206 (IQR: 132–448) (Table 2). The median impact factor of publications was 18 (IQR: 9–34). More than one third (n = 25) reported a favorable result for the primary outcome.

3.5. *Public availability of trial results according to academic sponsor category*

In the Kaplan-Meier analysis, the cumulative probability of results availability was 57% for cooperative groups, 41% for European organizations, 32% for oncologic hospitals, and 17% for university hospital at 10 years from the beginning of trials (log rank test p = 0.0006) (Fig. 3). When university hospitals collaborated with cooperative groups, the cumulative probability of results availability achieved 59%. Similarly for oncologic hospitals, it reached 74% (Supplemental Fig. 1). The variability in the availability of trial results does not appear to be explained by differences in the key characteristics of the trials conducted by each academic sponsor (Table 2).

European organizations were more likely to post their trial results (n = 4, 19%, of which two were also published, p = 0.0006). Cooperative groups in collaboration with European organizations and university hospitals each posted one trial on ClinicalTrials.gov (Table 2).

Considering the 73 publications, cooperative groups were involved in half of them (37/73), oncologic hospitals in 27% (20/73), university hospitals in 12% (9/73) and European organizations in 10% (7/73) (Fig. 2). Of the trials run by cooperative groups without collaboration (n = 46), 56% (19/34) and 33% (4/12) were published for GCO and for non-GCO members respectively.

The median impact factor for cooperative group publications was 18 (IQR: 10–28), 14 (5−25) for oncologic hospitals, 10 (3−24) for university hospitals and 35 (35−44) for European organizations (p = 0.007) (Table 2). In the case of collaborations with cooperative groups, the median impact factor of publications increased both for oncologic hospitals and university hospitals (26 (20−28) and 18 (12−52), respectively). For publications of trials run by cooperative groups without collaboration (n = 23), the median impact factor for GCO publications was 18 (11−27) and for non-GCO members it was 8 (6−13).

The proportion of favorable primary outcome results reported was similar between the academic sponsor categories, i.e. about 40%, except for university hospitals where it was zero (Table 2). The time from trial

Table 2
Trial characteristics, availability of trial results and publication characteristics considering the type of sponsor.

Characteristics	All included trials	Cooperative groups	University hospitals	European organizations	Oncologic hospitals
Number of trials (n, %)	211 (100)	69 (33)	50 (23)	21 (10)	71 (34)
Number of randomized patients *	206 [132–448]	229 [142–448]	219 [80–321]	707 [359–1182]	150 [126–276]
Phase 2–3 and Phase 3 trials (n, %)	135 (64)	48 (70)	39 (78)	13 (62)	35 (49)
Pharmacological trial (n, %)	149 (71)	63 (91)	26 (52)	19 (91)	41 (58)
Main type of cancer	Breast	Hematology	Digestive	Urology	Breast
	Digestive	Lung	Hepatology	Neurology	Digestive
	Hematology	Digestive	Hematology	Breast	ORL
	Lung		Breast	Gynecology	
Stage of cancer: Surgical	57 (32)	8 (18)	18 (42)	5 (33)	26 (38)
Advanced and metastatic	83 (47)	29 (64)	14 (33)	8 (53)	32 (47)
Global availability of results (n, %)	77 (36)6 (3)73 (35)	38 (55)1 (1.4)37 (53.6)	10 (20)1 (2)9 (18)	11 (52)4 (19)7 (33)	20 (28)0 (0)20 (28)
Posted results on CT registry (n, %)					
Publications (n, %)					
Impact factor of publication *	18 [9–34]	18 [10,28]	10 [3,24]	35 [35,44]	14 [5,25]
Delay between start date and publication *§	7.2 [5.2–9]	7.4 [5.7–9]	5.6 [3.6–8.3]	7.6 [7–9.8]	7.1 [5–8.3]
Favorable primary outcome reported (n, %)	25 (34)	14 (38)	0 (0)	3 (43)	8 (40)

*median [IQR], § years, CT clinical trial, ¤ 2 trials were posted and published

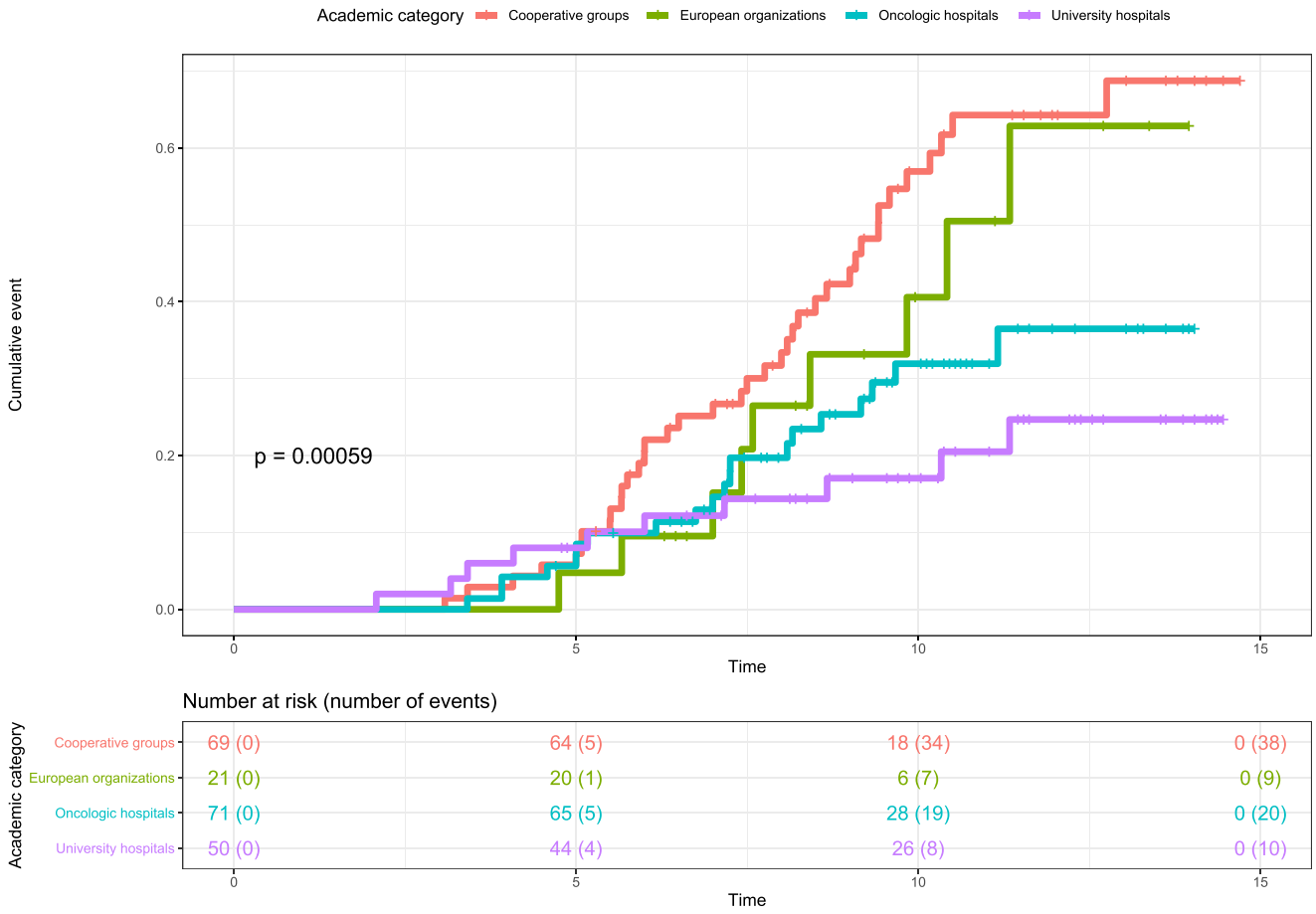

Fig. 3. Cumulative probability of availability of randomized trials results according to academic sponsor.

initiation to publication averaged 7 years for all academic sponsor categories (p = 0.34), and there was no statistically significant difference for the number of patients randomized (p = 0.09).

4. Discussion

Between the first of January 2005 and the first of January 2015, 211 academic phase 2 and 3 randomized trials in oncology were started in France. Only 36% of these trials had publicly available results on October 2019. French cooperative groups were involved in 69 trials; in a third of these, cooperative groups were involved in collaboration with other partners. Oncologic hospitals conducted one third of the trials, university hospitals less than a quarter, and European organizations ten percent. Ten years on from the beginning of trials, cooperative groups provided twice as many trial results as oncologic hospitals and four times as many as university hospital. Collaboration with cooperative groups appears to be favorable for the dissemination of trial results.

Our results are consistent with those of Bourgeois [25] and Goldacre's studies [19]. Bourgeois et al. conducted an observational study of safety and efficacy trials for anticholesteremics, antidepressants, antipsychotics, proton-pump inhibitors, and vasodilators conducted between 2000 and 2006 using ClinicalTrials.gov and assessed publication according to, amongst other factors, funding source [25]. Among 546 drug trials, 346 (63%) were primarily funded by industry, 74 (14%) by government sources, and 126 (23%) by nonprofit or nonfederal organizations. Overall, 362 (66.3%) trials had published results. Rates of trial publication within 24 months of study completion ranged from 32.4% among industry-funded trials to 56.2% among nonprofit or nonfederal organization–funded trials without industry contributions (P = 0.005 across groups). Goldacre et al. performed a retrospective cohort study evaluating the publication of results on EU-CTR for trials for which the results were due, and in their analyses they considered the kind of sponsor involved [19]. Of 7274 trials where results were due, 49.5% (95% confidence interval 48.4–50.7%) reported results. Trials with a commercial sponsor were substantially more likely to post results than those with a non-commercial sponsor (68.1% v 11.0%, adjusted odds ratio 23.2, 95% confidence interval 19.2–28.2). Our search on ClinicalTrials.gov found that 35% of trials were sponsored by academic institutions, which is similar to the proportion reported in other studies not focused on oncology (37% in the Bourgeois study [25] and 45% in the Goldacre study [19]). We showed that almost two-thirds of randomized controlled trials in oncology conducted in France did not yield any public results, either on the registry platform or in scientific journals. A systematic review on publication rates from 2014 including 39 cohorts found journal publication rates of 46.2% (95% confidence interval 40.2–52.4%) for trials approved by ethics committees and 54.2% (42.0–65.9%) for trials on clinical trials registries [26]. These results are close to those of the Bourgeois study with a publication rate of 56.2% among nonprofit or nonfederal organization funded trials [25]. In our study, the availability of results at 10 years varied a lot depending on the academic sponsor, from 55% for cooperative groups to 17% for university hospitals, which explains our global result of 36% of availability. Likewise, clinical trial registries provided only results for 6 trials (3%), of which four were unpublished. As highlighted by Goldacre et al., compliance with the European Commission requirement for all trials to post results on to the EU-CTR within 12 months of completion is poor: results were reported for 11.0% of trials with a non-commercial sponsor (9.8–12.4%) [19]. Similar results were found for ClinicalTrials.gov [27]. Differences according to the kind of academic sponsor revealed in our study were previously highlighted by Goldacre in 2018 with an

important difference between reported results in EU-CTR for EORTC and university hospitals of Paris [19]. In the United States, Chen et al. found that the proportion of clinical trials published within 24 months of study completion ranged from 10.8% (4/37) to 40.3% (31/77) across academic institutions (mainly universities); the overall rate of results reporting ranged from 4.1% (5/122) to 55.4% (98/177) [14].

We found that one third of trials performed in oncology involved cooperative groups and that cooperative groups were involved in half of published trials. Similar results have been found in thoracic oncology with 47% of randomized trials sponsored by cooperative groups published [28]. When considering the results of trials, experimental superiority was found in 46% of non-industry sponsored trials, which is close to our 40% of favorable primary outcome results reported [28].

Our study has some potential limitations. First, we did not study industry-sponsored trials. Several studies have already investigated the publication rates of these trials [22,23,25]. Industry-sponsored trials have a well-oiled research machine with expertise in publishing and may be more comparable to cooperative groups than single-institution trials. The main results of our paper suggest that it might be better for small organizations to seek collaboration with cooperative groups to sponsor trials, rather than do so alone, since cooperative groups have better publication outcomes. Collaboration with industry could also be a solution, but in our paper we focused on academic research. Second, we only considered publications automatically indexed to the trial on ClinicalTrials.gov by the NCT Number and those added by the investigators on the registry website. We did not perform manual search of publications on PubMed or Embase, because 1) we wanted to apply a standardized search, 2) ascertainment of results publication by manual searches in academic journals cannot be done with perfect accuracy [19] and could favor one of the four academic categories, and 3) we believe that giving access to the results of their trials is one of the key missions of sponsors, either by mentioning the NCT number in the published abstract or by posting the publication on ClinicalTrials.gov. We may have underestimated the number of publications, though this underestimation would apply equally to each academic category. Third, we considered the start date of the trial between January 2005 and January 2015 as inclusion criteria and we performed the search of publications on October 4th, 2019. So, for the last included trials, the minimal delay was in theory 4.8 years and we finally obtained a median delay between the start date of trials and the search of publications of 9 (IQR 7–11) years. We did not consider the completion date because this date was not always available on ClinicalTrials.gov. In the study by Goldacre et al., the completion date was missing in 30% of cases [19]. In our study, it was missing for 10% of the included trials, and when available in another 10% this date was erroneous (after the publication date). Lastly, we focused on the example of France, and our findings might not necessarily be applicable to other countries. We do, however, believe that our results together with results from previous studies make it reasonable to assume that cooperative groups' input is the same worldwide.

Our study has several implications. The results of French cancer trials sponsored by cooperative groups were more often published than trials sponsored by other entities. One explanation could be that cooperative groups are more structured, with sufficient staff for each task (clinical research nurses, statistical and legal support) dedicated to research dissemination. Indeed, it is now very challenging to sponsor randomized trials because the logistics involved are increasingly complex. Thus, publication of research is to some extent contingent on resources. We found that the more structured cooperative groups in France, GCO members, sponsored more trials than the non-GCO members (74% (34/46) versus 26% (12/46) trials), and published their trial results more (56% (19/34) versus 33% (4/12)). Moreover, collaboration with French cooperative groups increased the cumulative probability of results availability for university hospitals and for oncologic hospitals. Considering that running a trial is complicated and resource-consuming, collaboration between academic partners seems to be one solution. Collaboration with industry could be another alternative in some situations and is currently increasing with cooperative groups which are well-structured for such partnerships.

The difference in the cumulative probability of availability of randomized trials results according to academic sponsor did not seem to be explained by the trial characteristics. The proportion of phase 2–3 and phase 3 trials was higher for university hospitals which had the lowest results availability. The repartition of cancer type by sponsor was homogenous and did not induce a higher likelihood of publication just by virtue of site specific bias. Compared to French cooperative groups, university hospitals and oncologic hospitals had lower rate of pharmacological trials and 40% of their trials assessed patients at a surgical stage (details in Supplemental Table 1). Regarding methodology, university hospital trials had an important variability of outcomes (48% of other outcomes, Supplemental Table 1). French cooperative groups seem to be an asset for academic oncological research. It is likely that these results observed in France can be transposed in other countries which have large cooperative oncological groups.

5. Conclusion

Cooperative groups have become essential in the academic oncological research landscape. In France, they published more of their results than the other academic groups. This is probably because they are a well-oiled research machine with publishing expertise and a broad research-industry partnership that allows them to carry out research projects at a much higher rate than individual centers.

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CRediT authorship contribution statement

Perrine Créquit: Conceptualization, Data curation, Writing- Protocol and Original draft preparation. **Alexandre Vivot:** Data Analysis, Reviewing and Editing. Writing-Protocol. **Jules Grégory:** Reviewing and Editing. Writing-Protocol. **Bernard Milleron:** Supervision. Validation. Interpretation of the results. Writing- Reviewing and Editing.

Authors's disclosure

The authors have declared no conflicts of interest.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.jcpo.2022.100347.

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