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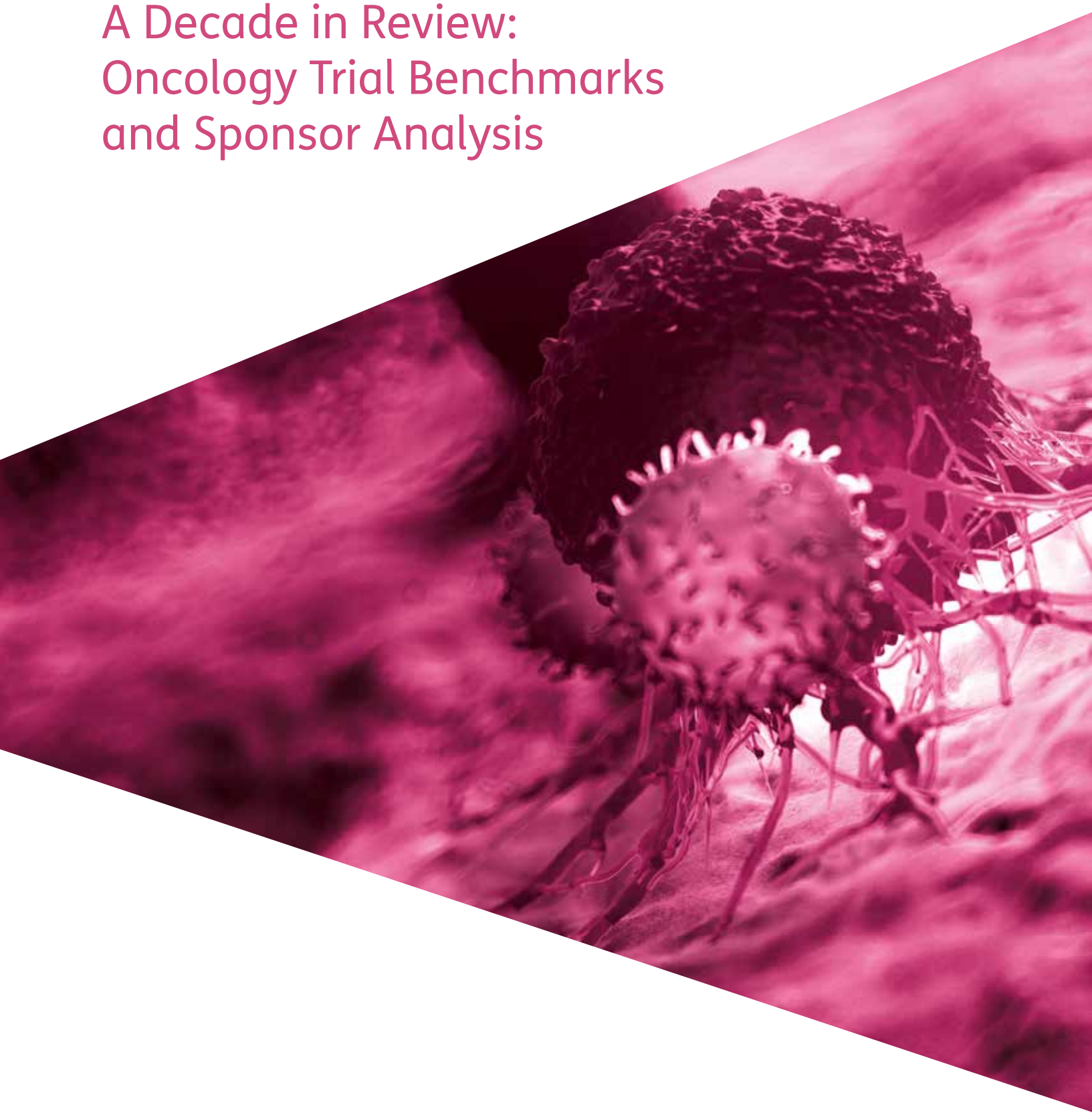
A Decade in Review: Oncology Trial Benchmarks and Sponsor Analysis



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Overview

The average cost of bringing a new drug to market continues to rise, with varying levels of investments across the highly competitive biopharmaceutical industry. To assess the potential effect of varying investments on trial activity and operations, this article reviews trial benchmarks within the active oncology therapeutic area. Industry-sponsored clinical trials across all oncology indications covered by Informa Pharma Intelligence's Trialtrove were assessed, comparing metrics by company size based on pharma sales, and the identical benchmarks for breast cancer and rare cancers were also analyzed.

Introduction

Drug development is a costly endeavor, in part due to increasingly complex protocols.[1] Large pharmaceutical companies, specifically the Top 20 companies by pharma sales in 2016 ("Top 20 Pharma"), invested an average of $5.0bn into their R&D expenditures in 2016, ranging from $1.9bn to $10.1bn. In sharp contrast, companies outside of the Top 20, referred to as "All Other Pharma" (AOP), fueled their R&D with an average of $150.7m, and showed a wider range of $20m to $4.5bn. Ten years prior, the Top 20 Pharma companies in 2007 invested an average of $3.9bn (range of $581m to $8.1bn), while AOP averaged $251.9m (range of $1.1m to $1.9bn).[2]

In addition to the costs of R&D, competition within the pharma industry continually grows, and is compounded by the threats of biosimilars and generics. Coupled with incentives provided by regulators to encourage orphan drug development, companies are increasingly expanding their investments beyond diseases with high prevalence and into more niche markets.

Considering these differences in investments and interests, we investigated the impact on the volume and size of clinical trials within the industry's most active therapeutic area of oncology, evaluating whether large investments made by Top 20 Pharma translate into more trial activity, larger patient accruals, and geographically broader trials in comparison to the rest of pharma over the past 10 years. This analysis examines metrics across all oncology in addition to the highly prevalent disease of breast cancer and niche area of rare cancers.

1. Getz KA, Campo RA (2017) New Benchmarks Characterizing Growth in Protocol Design Complexity. Ther Innov Regul Sci, 52(1), 22–28. Available from: 10.1177/2168479017713039 [Accessed March 7, 2018].
2. Scrip 100 (2017) Scrip 100 Analysis: Sales Up, Profits Down – But Is It Real? Available from: https://scrip.pharmaintelligence.informa.com/scrip100/scrip100 [Accessed March 7, 2018].

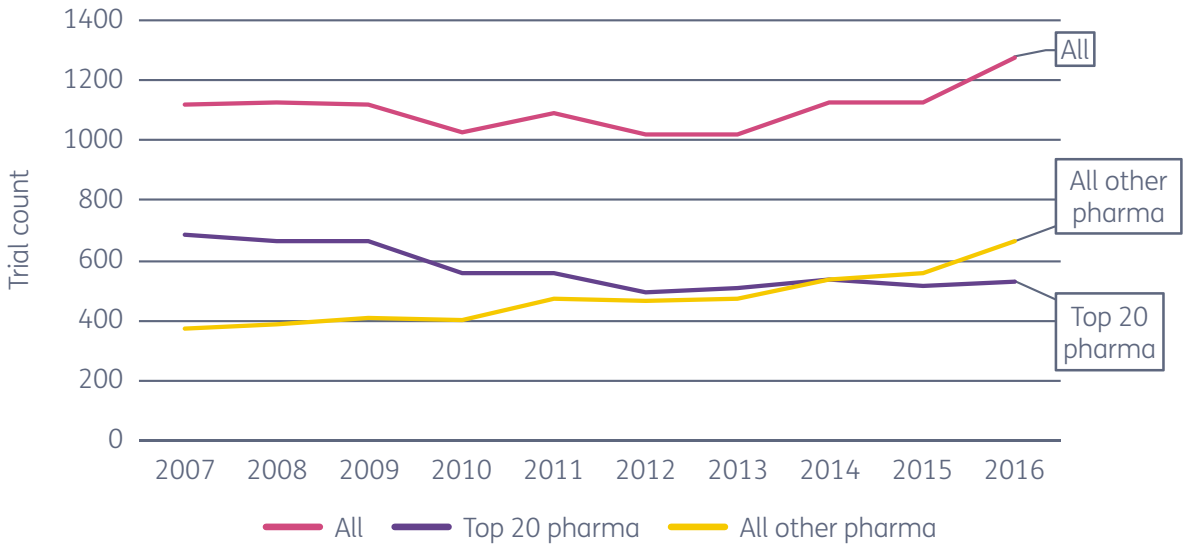
Methodology

This analysis reviewed Phase I, II, and III clinical trials across all industry-sponsored oncology indications covered by Informa Pharma Intelligence's Trialtrove with a reported start date between January 2007 and December 2016. The data set is limited to trials that included at least one industry company categorized as Top 20 Pharma or AOP based on pharma sales reported in 2016.[3] The analysis focuses on companies within drug development, and excludes those specialized in generics, medical devices, and diagnostics. Metrics examined in this analysis include trial volume, total trial duration, enrollment duration, patient accrual, number of countries, and number of sites identified by Informa Pharma Intelligence's Trialtrove, Trialpredict, and Sitetrove, a commercially available intelligence resource that consolidates information from more than 70 countries and over 35,000 publicly available sources.[4]

Trends in Oncology Trials Initiated During 2007–16

Between 2007 and 2015, industry trial starts remained relatively flat for the oncology diseases included in Trialtrove, hovering between 1,000 and 1,200 (Figure 1). Only in 2016 did trial starts exceed the 1,200 benchmark. When separating activity by sponsor types of Top 20 Pharma and AOP, a declining trend is observed for the former, with a complementary positive growth trend for the latter. The growth in oncology trial starts appears to have been fueled by the growth in AOP trial activity.

Figure 1. Oncology trial starts, 2007–16

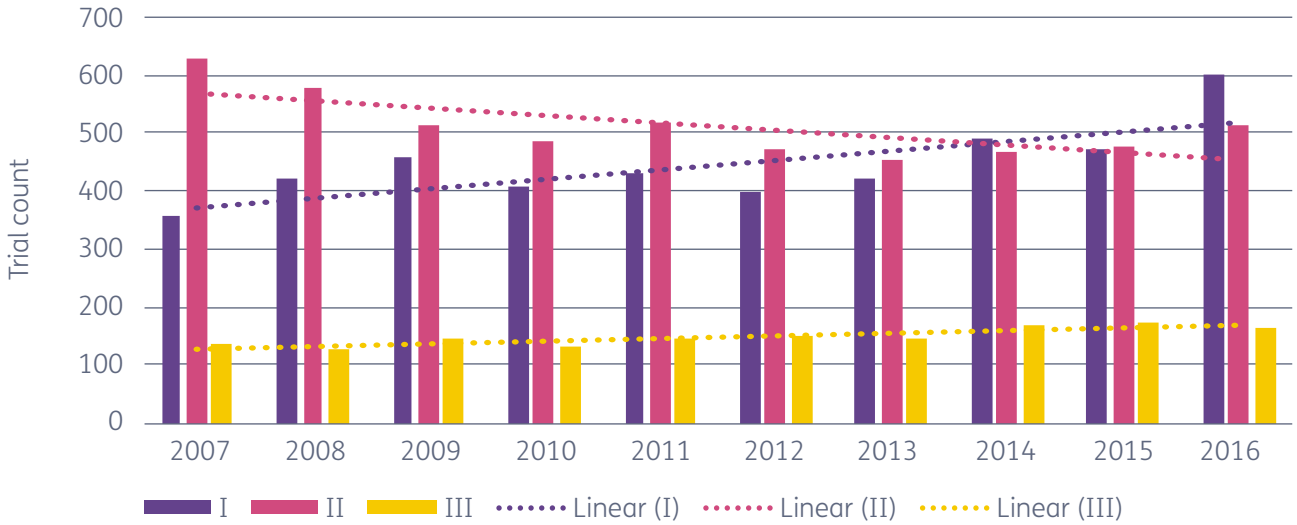


Source: Trialtrove®, December 2017

3. Sponsor type categories are mutually exclusive. Trials within the Top 20 Pharma group include at least one sponsor/collaborator designated as Top 20 Pharma, and exclude trials with AOP as a sponsor/collaborator. Likewise, trials categorized as AOP include at least one AOP sponsor/collaborator, and exclude trials with a Top 20 Pharma sponsor/collaborator. Trials that include both sponsor types are only included in the category of All.
4. Wong CH, Siah KW, Lo AW (2019) Estimation of clinical trial success rates and related parameters. Biostatistics, 20(2), 273–86. Available from: 10.1093/biostatistics/kxx069 [Accessed April 9, 2019].

Over the past 10 years, Phase I industry-sponsored trials showed an increasing trend toward growth (Figure 2). Phase II trial starts, on the other hand, exhibit a decreasing trend between 2007 and 2016. Of note is the fact that the magnitude of Phase II trial starts in most of the decade analyzed was higher than seen for Phase I trial starts. Phase III trial starts were consistently lower than Phase I and II, with a very slight positive growth trend.

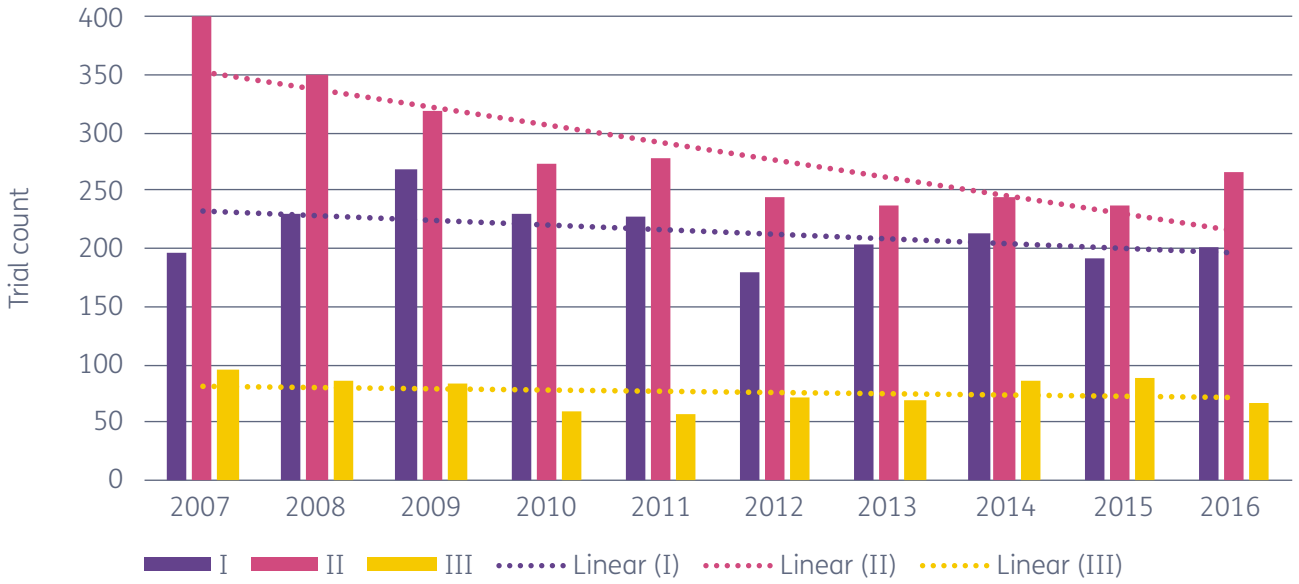
Figure 2. Oncology trial starts: All sponsor types, by phase, 2007–16



Source: Trialtrove®, December 2017

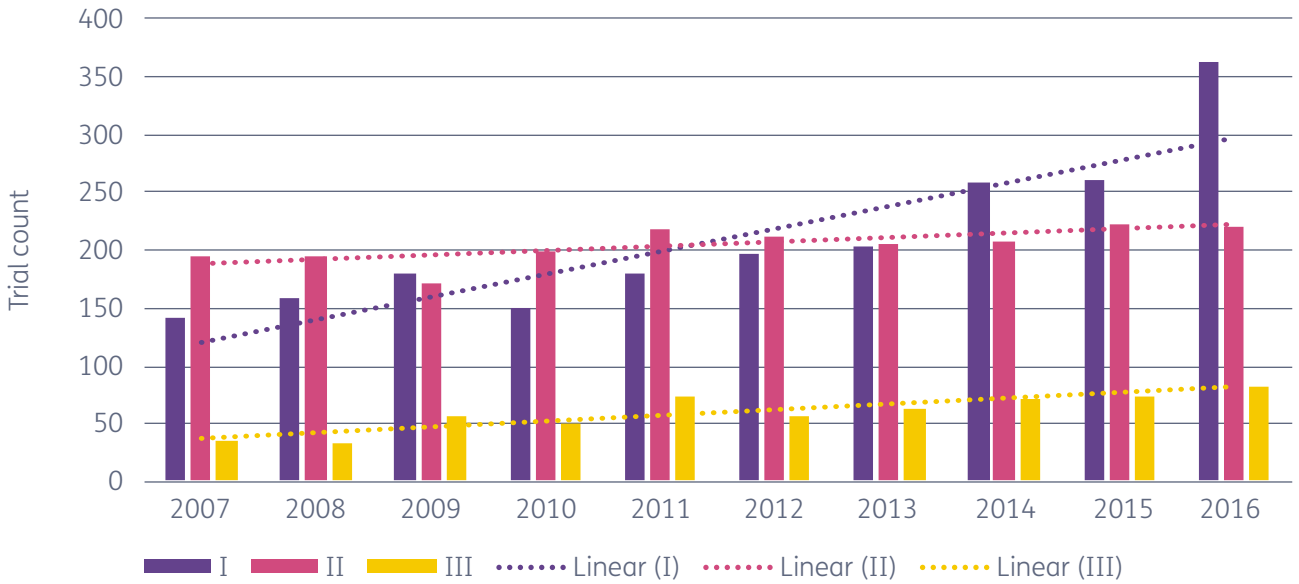
Among the trials initiated by Top 20 Pharma, both Phase I and Phase II trials started during the 10-year period show a declining trend (Figure 3a), while the linear trend for Phase III trials initiated each year shows far less of a negative slope. For AOP trials, a strong positive trend is seen for Phase I trial starts (Figure 3b), with a flatter growth for Phase III trials, while Phase II trial starts hover around 200 trials for each of the 10 years analyzed.

Figure 3a. Oncology trial starts: Top 20 pharma, by phase, 2007–16



Source: Trialtrove®, December 2017

Figure 3b. Oncology trial starts: AOP, by phase, 2007–16

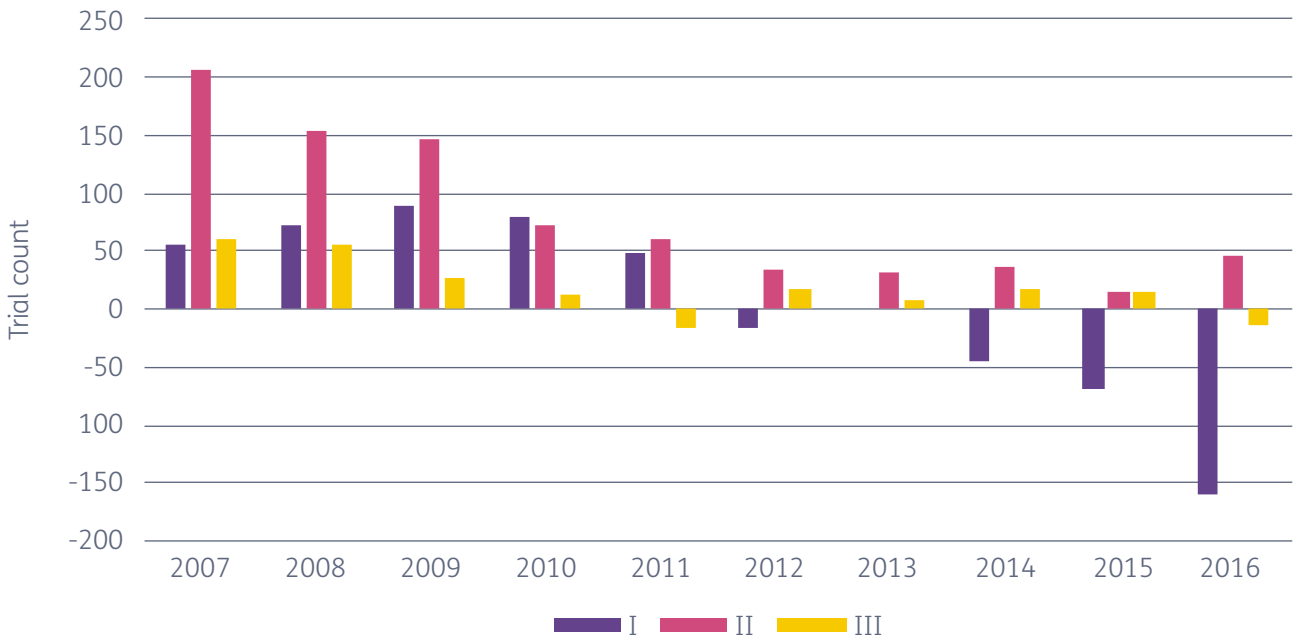


Source: Trialtrove®, December 2017

For the period of 2007–10, Top 20 Pharma initiated more trials at each phase compared to AOP (Figure 4). However, from 2014 through 2016, AOP initiated more Phase I trials compared to Top 20 Pharma, with 46, 69, and 161 more trials, respectively.

The "flip" from Big Pharma starting more Phase I oncology trials to AOP was observed between 2011 and 2012, with an equal number of trials started by each sponsor type in 2013.

Figure 4. Oncology trial starts: Top 20 Pharma minus AOP, by phase, 2007–16



Note: Vertical bars represent the difference between the trial starts by Top 20 Pharma and AOP for each year and for each phase. Positive differences indicate where trial counts for Top 20 Pharma exceeded AOP, while negative histogram bars indicate when AOP trial counts exceeded Top 20 Pharma.

Source: Trialtrove®, December 2017

Across all oncology trials initiated over the past 10 years, average trial durations[5] showed a trend for shorter and shorter trials; this is true for Phase I and Phase II trials throughout the decade (Table 1). For Phase III trials, there was a slight increase in average trial duration from 2009 to 2010, followed by shorter average durations for each successive year through 2016. The absolute numbers of trials where a documented start date and end date were available in the public domain are relatively small; and for the trials started in 2014 and later, many are still ongoing, especially Phase III trials. Among the trials for which these dates were available, the majority were sponsored by Top 20 Pharma (Data not shown).

5. The trial duration is calculated based on the trial start date, or the date a trial initiated, to the trial end date. In Trialtrove, the end date is defined as the primary completion date or the date on which primary endpoints are reported.

The difference in average trial durations between Top 20 Pharma and AOP indicates that the large companies do not complete trials faster (Table 1), with a few exceptions such as those seen for Phase III trials in 2008–10 and for Phase I trials in 2013. In 2014, Top 20 Pharma and AOP had minimal differences in average trial durations across all phases; however, Top 20 Pharma reverted to longer completions for Phase II and III trials in the following year. As previously stated, many trials remain ongoing, and trends in recent years may shift as more trials complete.

When examining the differences in enrollment durations between Top 20 Pharma-sponsored and AOP-sponsored trials, enrollment differences are mostly positive for AOP for Phase II trials, except for three years: 2007, 2010, and 2013. AOP enrolled into their Phase II trials more quickly for seven of the 10 years (Table 1). The difference in average enrollment durations for Phase III trials markedly differs from Phase II, as indicated by seven years where Top 20 Pharma enrolled Phase III trials more quickly. The Top 20 Pharma group shows significantly faster enrollments of five months or more in 2010, 2012, and 2014.

Table 1. Oncology average trial and enrollment durations, by Top 20 Pharma and AOP, 2007–16

	Average Trial Duration (months)								
	All Sponsors			Top 20 Pharma			All Other Pharma		
Year	I	II	III	I	II	III	I	II	III
2007	45.15	50.24	57.18	45.23	51.75	60.42	43.15	47.18	50.36
2008	41.65	45.26	56.88	42.99	46.16	52.52	39.88	43.65	69.58
2009	38.29	45.59	49.47	39.32	46.48	48.28	35.34	43.56	51.16
2010	36.90	43.16	50.50	37.89	46.16	48.53	34.09	38.01	51.86
2011	34.07	40.90	44.16	34.88	43.44	45.83	32.13	37.41	42.07
2012	31.27	37.87	39.88	31.67	38.39	38.74	30.47	37.20	39.13
2013	25.50	33.12	35.24	23.65	33.97	34.46	26.98	31.78	34.97
2014	21.26	28.19	29.24	21.27	27.94	28.80	21.23	28.12	29.44
2015	15.24	20.73	21.01	15.20	22.94	23.23	15.20	18.21	16.71
2016	8.38	12.97	9.83	8.98	13.13	9.78	7.69	12.92	9.90

	Average Enrollment Duration (months)								
	All Sponsors			Top 20 Pharma			All Other Pharma		
Year	I	II	III	I	II	III	I	II	III
2007	29.49	25.36	36.43	28.26	24.58	38.53	30.06	27.61	34.02
2008	24.97	26.34	33.73	22.78	26.59	32.96	28.62	25.11	34.38
2009	23.29	25.42	29.88	24.66	26.11	29.26	21.04	24.28	30.55
2010	25.56	26.65	36.22	24.62	25.48	33.09	24.02	27.74	38.39
2011	25.72	25.32	30.04	26.72	27.36	29.85	24.12	22.43	28.10
2012	26.69	27.77	25.76	26.12	28.92	23.52	26.93	26.07	30.25
2013	24.10	24.03	27.59	25.06	22.81	26.36	23.28	26.21	28.48
2014	17.80	22.05	20.99	15.38	22.72	18.49	19.80	21.15	24.54
2015	19.52	20.01	22.35	19.02	21.53	21.33	19.49	17.67	24.11
2016	12.57	15.39	21.70	11.30	17.31	26.22	12.89	13.22	18.93

Note: Shaded cells indicate shortest durations between the two sponsor types. Metrics for 2016 are likely lower than other years due to ongoing trial activity.

Source: Trialtrove®, December 2017

In terms of trial size by patient accrual, Top 20 Pharma typically enrolled more subjects than AOP during the decade, and across all phases, which is in line with the longer trial durations observed in this period. The average accrual for Phase I trials sponsored by Top 20 Pharma remained consistent, hovering between 45 to 66 patients per trial, except 2011 which had an average of approximately 81 patients. The average size of AOP Phase I trials was initially smaller in comparison, but slowly grew over time and increased to similar averages to Top 20 Pharma. Top 20 Pharma enrolled 3–45 more average patients per trial than AOP, excluding 2013 where the average patient difference was -2. The average size of Phase II trials for both sponsor types grew over the period, with Top 20 Pharma outpacing AOP for most years, enrolling 1–83 more patients on average per trial. The exception was seen in 2012–14 where the average patient difference was -1 to -16. The starkest difference is with Phase III trials. Although it does not follow a clear pattern over the time period, on average, Top 20 Pharma out-enrolled AOP by 250 patients, ranging from 123 to 461 (Data not shown).

With regard to the trial size by geographic breadth, there is a slight positive trend in involving more countries across the 10-year period of this analysis (Table 2); this is especially true for Phase II and III trials. The average number of countries involved in Phase I trials has remained relatively constant, with a range of 1.3 to 1.9 countries.

The average number of countries included in trials sponsored solely by Top 20 Pharma surpassed the AOP-only sponsored trials for every phase and for every year (Table 2). Phase III trials sponsored by Top 20 Pharma averaged between 3.5 to nearly 12 countries higher than trials sponsored by AOP.

The magnitude of Phase III geographic breadth for Top 20 Pharma-sponsored trials cannot be explained as an artefact of differences in absolute numbers of trials initiated by each sponsor data set (refer to Figures 2a, 2b, and 3). This investment by large pharma in more global trials has been evident throughout the 10 years of data in this analysis.

One might assume that Top 20 Pharma's involvement of sites in more countries would also be reflected in larger average numbers of identified sites compared to AOP, and the data corroborate this, with Phase III showing the largest net difference.[6] (Table 2).

Table 2. Country and site utilization for oncology trials, by Top 20 Pharma and AOP, 2007–16

	Average Number of Countries per Trial								
	All Sponsors			Top 20 Pharma			All Other Pharma		
Year	I	II	III	I	II	III	I	II	III
2007	1.35	2.11	10.07	1.39	2.13	10.67	1.23	1.95	6.86
2008	1.28	2.36	11.06	1.37	2.66	12.84	1.17	1.94	6.59
2009	1.45	2.47	10.96	1.57	2.35	11.79	1.20	2.24	8.24
2010	1.49	2.18	11.49	1.61	2.46	14.07	1.23	1.77	7.20
2011	1.69	2.55	11.97	2.02	3.19	15.68	1.24	1.59	8.64
2012	1.67	2.99	12.52	2.01	3.88	15.80	1.26	1.90	7.51
2013	1.89	2.86	12.21	2.43	3.47	14.84	1.32	2.12	7.93
2014	1.60	2.94	13.22	2.01	3.56	15.65	1.23	2.12	9.64
2015	1.76	3.56	14.40	2.19	3.91	18.83	1.42	3.05	7.05
2016	1.68	2.31	10.60	2.47	2.57	14.13	1.23	2.03	6.55

	Average Number of Identified Sites per Trial								
	All Sponsors			Top 20 Pharma			All Other Pharma		
Year	I	II	III	I	II	III	I	II	III
2007	3.18	14.55	117.74	2.90	15.28	132.73	3.13	11.59	76.60
2008	3.26	16.16	121.12	3.29	19.03	143.38	3.01	11.38	74.00
2009	4.06	16.97	103.35	4.27	17.07	112.62	2.97	13.95	76.91
2010	4.14	14.83	100.05	4.80	15.46	126.75	2.84	13.83	55.74
2011	4.71	17.54	104.71	5.55	21.13	146.27	3.17	11.54	68.61
2012	4.74	17.54	105.14	5.57	21.57	117.86	3.77	12.15	80.73
2013	6.00	19.32	128.68	7.13	21.61	151.88	4.72	16.61	88.32
2014	5.12	26.86	111.68	6.12	35.26	109.28	4.08	15.79	87.00
2015	6.33	20.37	133.81	7.24	21.05	170.81	5.30	18.61	74.57
2016	5.10	13.76	96.72	7.24	14.81	132.12	3.76	12.65	60.89

Note: Shaded cells indicate largest number of countries or sites used per trial between the two sponsor types.

Source: Trialtrove®, December 2017

6. The number of identified sites is defined as the sum count of the named sites and investigators found to be associated with the clinical trial, and confirmed by Sitetrove. This absolute count of sites is identified by Sitetrove from public domain sources that include, but are not limited to: trial or trial results registries, curricula vitae, press releases, meeting abstracts, and published articles.

Trends in Trial Metrics for Breast Cancer

To assess whether 10-year trends across all oncology trials are reflective of individual types of cancers, we examined benchmarks for breast cancer trials. Across all sponsor types, there is a decreasing trend for Phase I and II, and a slight increasing trend for Phase III starts (data not shown), which differs somewhat from trends observed across the therapeutic area (refer to Figure 1). For trials sponsored solely by Top 20 Pharma, decreasing trends in trial starts are noted for each trial phase (Figure 5a). This is in stark contrast to the year-over-year trend seen for AOP trials (Figure 5b), where increasing trends are seen for each phase.

Figure 5a. Breast cancer trial starts: Top 20 Pharma, by phase, 2007–16

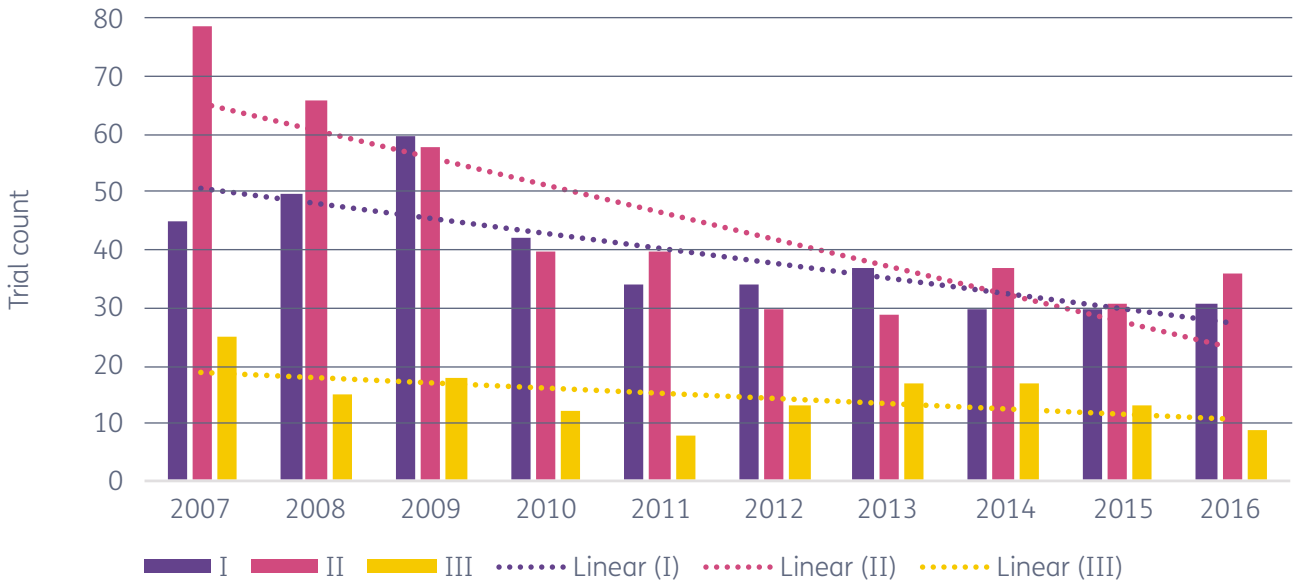
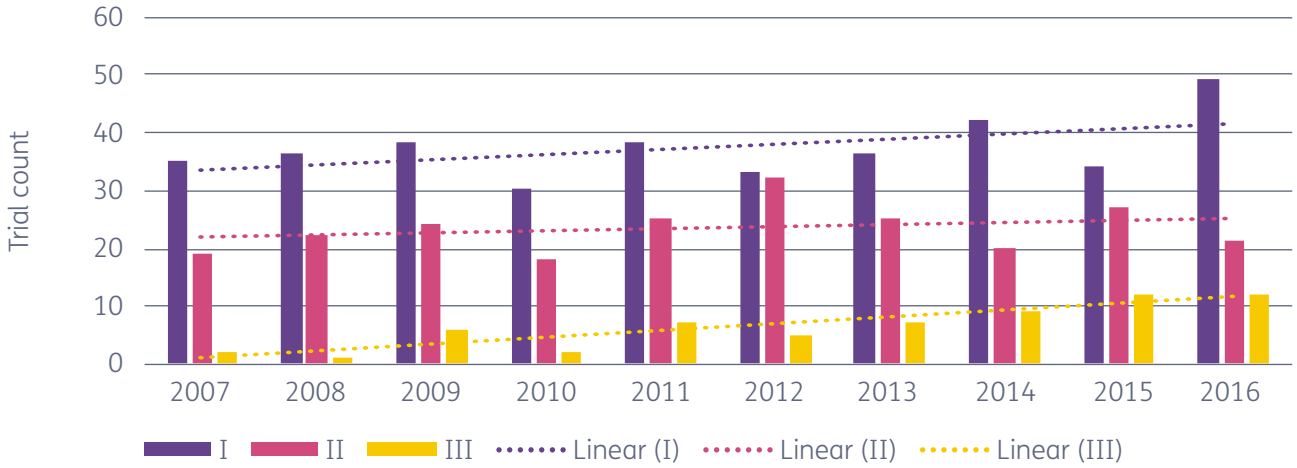


Figure 5b. Breast cancer trial starts: AOP, by phase, 2007–16



Source: Trialtrove®, December 2017

When comparing breast cancer trial durations over the decade, AOP, on average, completed trials more quickly compared to Top 20 Pharma (Table 3). Average trial duration differences were positive for Phase I and II trials for nearly all 10 years, indicating AOP's ability to run trials more quickly. Top 20 Pharma averaged longer Phase III trials compared to AOP for six of the 10 years. For the three-year period of 2008–10, and for trials initiated in 2013, Top 20 Pharma had faster average trial durations.

Table 3. Breast cancer average trial durations, by Top 20 Pharma and AOP, 2007–16

	Average Trial Duration (months)								
	All Sponsors			Top 20 Pharma			All Other Pharma		
Year	I	II	III	I	II	III	I	II	III
2007	46.27	52.83	67.93	48.88	55.02	68.57	41.19	48.19	53.20
2008	46.48	41.09	63.79	50.13	43.42	59.67	40.57	33.61	73.30
2009	43.81	43.23	52.11	47.06	43.03	49.54	37.94	42.68	59.53
2010	41.22	42.79	57.35	42.01	43.40	54.06	38.03	37.87	76.10
2011	43.89	37.64	45.89	46.66	42.04	54.81	41.73	29.69	40.47
2012	38.42	41.02	40.28	40.76	43.71	44.55	35.00	39.52	34.63
2013	32.57	31.75	35.03	32.61	31.49	33.54	32.14	30.68	41.73
2014	28.46	30.05	32.85	27.46	30.91	33.63	29.00	27.55	30.83
2015	18.01	22.01	52.31	21.28	24.09	57.21	14.73	20.77	37.61
2016	11.10	17.00	8.60	7.73	3.77	8.60	12.78	23.62	N/A

Note: Shaded cells indicate shortest durations between the two sponsor types. Metrics for 2016 are likely lower than other years due to ongoing trial activity.

Source: Trialtrove®, December 2017

Breast cancer trials conducted by Top 20 Pharma exhibited longer trial durations, which could be due in part to the fact that their trials generally enrolled more patients. In the years that Top 20 Pharma had larger accruals than AOP, the average patient differences ranged between 4–145 for Phase I, 17–541 for Phase II, and 101–1,527 for Phase III. The years where AOP had larger average accruals than Top 20 Pharma for each trial phase are: 2013–14 for Phase I; 2007–09, 2012, and 2014–15 for Phase II; and 2010–11 for Phase III. Of note, only two Phase III trials are included in the set for AOP-sponsored trials in 2010, one of which is a large prevention study that enrolled 25,874 participants (Data not shown).

In line with trends observed across the therapeutic area as a whole, Top 20 Pharma consistently involved a larger average number of countries compared to AOP, as well as a greater average number of sites (Data not shown).

Rare Cancer Trials

An extensive R&D effort has been directed toward rare cancer diseases over the past 10 years or more. Due to limited trial volumes for individual rare cancers, this analysis reviewed metrics across all rare cancers covered by Trialtrove at the time that the data were analyzed. Rare cancer solid tumor diseases included in Trialtrove are: esophageal, gastric, liver, small cell lung, ovarian, pancreatic, osteosarcoma, GIST, renal, soft tissue sarcoma, and testicular cancers. Also included are the blood-borne cancers: acute myelogenous leukemia, chronic myelogenous leukemia, Hodgkin's lymphoma, mesothelioma, and multiple myeloma.

The average differences in trial starts between sponsor type for each year clearly demonstrate the shifting dynamics in these rare cancer diseases (Table 4). During the first four years, Top 20 Pharma initiated more trials in each of the phases. From 2012 onward, AOP initiated significantly more Phase I trials, and in some years more Phase II and III trials. Comparing trial starts in 2008 with those in 2014, Top 20 Pharma initiated 22 more Phase I trials than AOP, 54 more in Phase II, and 24 more in Phase III; in 2014, those numbers dropped to -39, -17, and -15, respectively. While these data do not represent all of the rare cancer diseases, the sampling of 16 types is likely to be representative of the domain as a whole.

Table 4. Rare cancer trial starts, by Top 20 Pharma and AOP, 2007–16

	Total Trials Started per Year								
	All Sponsors			Top 20 Pharma			All Other Pharma		
Year	I	II	III	I	II	III	I	II	III
2007	197	224	41	99	130	29	83	82	11
2008	231	217	54	117	128	37	95	74	13
2009	226	172	43	132	108	27	85	54	16
2010	195	194	43	107	101	18	72	88	16
2011	194	189	40	96	91	15	84	87	19
2012	184	160	43	77	81	14	94	68	21
2013	169	173	34	69	84	12	91	86	15
2014	211	150	49	79	63	15	118	80	30
2015	190	176	58	65	83	28	113	83	22
2016	235	190	58	77	94	23	143	84	28

Note: Shaded cells indicate largest trial counts between the two sponsor types.

Source: Trialtrove®, December 2017

Across these rare cancer trials, for Phase III trials, Top 20 Pharma sponsors had average trial durations that were shorter than AOP in eight of the 10 years (the exception years were 2007 and 2016; Table 5). For Phase II trials, Top 20 Pharma had only three years where they had shorter average trial durations: 2007, 2010, and 2013. Top 20 Pharma's average Phase I trial durations were shorter for six of the 10 years.

Table 5. Rare cancer average trial durations, by Top 20 Pharma and AOP, 2007–16

	Average Trial Duration (months)					
	Top 20 Pharma				All Other Pharma	
Year	I	II	III	I	II	III
2007	29.68	23.76	40.73	34.85	29.06	32.19
2008	22.77	25.96	31.10	29.97	25.29	36.98
2009	30.57	25.03	23.36	24.91	23.21	25.63
2010	24.64	27.03	30.39	19.16	29.99	35.35
2011	26.62	27.75	24.17	28.91	22.40	31.64
2012	26.89	31.12	32.39	25.56	25.88	37.99
2013	27.59	24.78	29.36	25.72	26.03	34.20
2014	22.33	25.29	13.60	23.17	23.15	27.99
2015	17.09	22.20	19.44	21.53	17.40	24.87
2016	14.86	17.63	41.11	9.08	15.27	16.87

Note: Shaded cells indicate shortest durations between the two sponsor types. Metrics for 2016 are likely lower than other years due to ongoing trial activity.

Source: Trialtrove®, December 2017

Top 20 Pharma consistently enrolled more patients on average for each phase and in each of the 10 years included in this analysis. For Phase I trials, the average patient difference ranged from 23 to 86; for Phase II, 23 to 126; and for Phase III, 348 to 627 (data not shown).

The geographic breadth of rare cancer trials over the 10-year period was not striking between Top 20 Pharma and AOP Phase I and II trials (average differences ranged from 0.1 to 1.8 countries). However, for Phase III trials, Top 20 Pharma listed sites in significantly more countries, ranging from 1.1 to a high of 11.1 more countries (in 2015; Data not shown). Top 20 Pharma sponsors also involved more sites compared to AOP. The difference in average numbers of reported sites for Phase I trials ranged from -0.2 to 5.1; 2007 was the year with the negative difference (Data not shown). Phase II trials consistently showed more sites, with average differences ranging from 2.5 to 8.7; Phase III trials ranged from -0.5 to 58.6, with the negative difference attributed to 2014. The data indicate that Top 20 Pharma invests in more global trials and more sites compared to AOP in rare diseases.

Conclusions

Overall, trial starts for oncology have remained relatively constant over the 10-year analysis period, with a slight rise seen in 2016. However, a shifting landscape is observed as Top 20 Pharma has contributed less and less to trial starts over time, with those sponsor companies sitting outside of the Top 20 starting more trials. Additionally, the larger investments from Top 20 Pharma did not consistently translate into shorter trial durations, primarily for Phase I and II trials. Shorter trial durations were achieved by Top 20 Pharma for the majority of their Phase III activity, or when honing in on rare cancer activity. Investments were reflected in various aspects of trial size, as oncology trials from Top 20 Pharma demonstrated larger numbers of patient accruals, trial sites, and countries in comparison to AOP sponsors.

In 2015 and 2016, AOP sponsors started between 40 to over 130 more trials in Phase I–III compared to Top 20 Pharma. Phase I trial starts by AOP equaled Top 20 Pharma in 2013, and significantly surpassed the larger companies in the following years. We assessed whether a significant number of these Phase I trials have study drugs that are acquired or licensed by Top 20 Pharma, and found that for breast cancer, 28 drugs moved to a later-phase trial with Top 20 Pharma, while five drugs moved to Top 20 Pharma through acquisition. In the rare cancers, 36 AOP drugs later had Top 20 Pharma sponsorship in trials, while 11 were acquired by Top 20 Pharma. Oncology has historically been the most active focus of deal-making (as reported by Informa Pharma Intelligence's Strategic Transactions and Medtrack) – with preclinical and Phase I deal volume accounting for 58% of deal activity in the last five years, compared to 44% in the 2008–12 period (Data not shown). These observations are all consistent with the notion that more innovation is occurring outside of Big Pharma.

Breast cancer AOP starts for Phase I trials also reflect the rise seen across all oncology, and provide fodder to support the oft-repeated assumption that innovation is happening within smaller companies. For Phase III trials, overall trial starts showed a slight overall positive trend (Data not shown), although Top 20 activity slightly decreases while AOP trials increased slightly. The rare cancer disease landscape also demonstrates the same shift in sponsor type commencing the most trials. During 2012–16, Phase I starts by AOP sponsors have increased, again suggestive of more innovation originating with smaller biopharma.

Biosimilar development was marginal across all cancer types, but did show an increase during the analysis period. In looking at the drugs, trials including a biosimilar increased from 19 during 2007–11 to 65 during 2012–16. When reviewing activity by sponsor type, biosimilar trials sponsored only by AOP grew from 12 in the first half of the decade to 47 in the latter half. In comparison, Top 20 Pharma starts grew from seven to 18 trials. Although biosimilar development has not been a significant driver for the growth in oncology trial activity to date, this key area of interest could become a larger contributing factor in time (Data not shown).

Considering the decreasing trial volume from Top 20 Pharma, these companies could be offsetting the lower trial counts with a larger number of patients enrolled into their trials. However, this was only observed with Phase II trials, which grew over the period, as the average number of patients per trial has generally decreased, with a few peaks in 2014–15.

While AOP typically demonstrated shorter trial durations than Top 20 Pharma across all oncology indications, this could be attributed in part to larger average patient accruals observed for Top 20 Pharma trials. Exceptions do exist for both metrics within specific years; however, no clear pattern was observed. Although Top 20 Pharma typically had larger accruals on average, this cohort of companies also invested more into their trials through larger geographic breadth and number of identified sites. Despite Top 20 Pharma's use of additional sites and countries to accommodate larger patient pools, AOP still managed to frequently outpace Top 20 Pharma with shorter Phase I and II enrollment durations, potentially speaking to the merit of conducting smaller trials. Of note, these metrics are dependent on the public disclosure of the country and/or site linked to the clinical trial. As such, the difference in metrics could also be a partial reflection of differing reporting rates by sponsor types.

Rare disease trial metrics, on the other hand, suggest that Top 20 Pharma sponsors are holding their own against AOP, with shorter trial durations while enrolling more patients and involving more sites. And despite an increased patient load, Top 20 Pharma had faster enrollment durations in a majority of years for Phase I and Phase III trials.

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Christine's role is to identify areas of unmet need in business intelligence for biopharma and healthcare clients, and to foster product, process and organizational data connectivity across Informa Pharma Intelligence. Christine also works with data from across the business to reveal trends or paradigm shifts that impact healthcare.

She joined Informa through the Citeline acquisition in late 2006. At that time, Christine headed editorial operations, product evolution, new product development and content strategy. She has written numerous white papers on trends in clinical development, pipeline rationalization, clinical trial terminations and business strategy using the wealth of data offered by Informa's intelligence products.

Christine's educational background is in biochemistry and biophysics. She earned a PhD from Purdue University and BS degree from the University of Scranton. Christine was on the faculty at Washington University School of Medicine in the departments of Biochemistry & Molecular Biophysics, Ophthalmology, and Anatomy & Neurobiology. She Ieft academia to pursue a career in market research and business analysis first at Decision Resources and then with Citeline/Informa.

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As a recognized thought leader, Doro heads the content marketing strategy and development for the Pharma Intelligence business at Informa. Drawing on nearly 15 years of experience supporting drug development, primarily as an Infectious and Genitourinary Disease analyst, for Citeline, Doro is acutely aware of the trends in the ever-changing pharmaceutical research landscape. As an analyst, Doro supported the editorial content of Citeline's pharmaceutical clinical trial products and assisted clients with competitive intelligence needs. Prior to Informa, Doro coordinated biomedical HIV prevention trials in Zimbabwe with the Women's Global Health Imperative at University of California, San Francisco (UCSF), and received her Master's degree in Public Health, with a specialty in Infectious Diseases, from the University of California, Berkeley.

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