FEATURE

# Clinical development success rates for investigational drugs

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**The most comprehensive survey of clinical success rates across the drug industry to date shows productivity may be even lower than previous estimates.**



Since the human genome was sequenced ten years ago, the number of compounds in development has increased 62% and total R&D expenditures have doubled[1–3]. And yet, the average number of new drugs approved by the US Food and Drug Administration (FDA) per year has declined since the 1990s. In 2012, 39 novel drugs classified as new molecular entities (NMEs) and biologic license applications (BLAs) were approved by the FDA[4]. Although this represents the highest number of approvals since 1997 and is nearly 50% above the average of 26 approvals per year over the past decade, 25% fewer NME and BLA drugs were approved on average in the past 10 years compared with the 1990s[5]. Several possible explanations for the divergence of R&D spending and new product approvals have been offered by professionals in the industry, such as unbalanced regulatory risk-benefit assessments, higher regulatory efficacy hurdles, commercial and financial decisions driving project termination, and the increased complexity and cost of clinical trials[6,7].

This article aims to measure clinical development success rates across the industry with a view to strengthening benchmarking metrics for drug development. The study is the largest and most recent of its kind, examining success rates of 835 drug developers, including biotech companies as well as specialty and large pharmaceutical firms from 2003 to 2011. Success rates for over 7,300 independent drug development paths are analyzed by clinical phase, molecule type, disease area and lead versus nonlead indication status.

Our results pinpoint weaknesses along the capital-intensive pathway to drug approval. Our hope is that they will prove useful in informing policy makers where to focus changes in regulation and strengthen valuation models used by industry and the investment community.

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## Analyzing success

To measure clinical development success rates for investigational drugs, we analyzed phase transitions from January 1, 2003 to December 31, 2011, in the BioMedTracker database. The BioMedTracker data set contained 4,451 drugs with 7,372 independent clinical development paths from 835 companies and included 5,820 phase transitions. The development paths comprised lead (primary) and nonlead (secondary) indications, with roughly 38% designated as nonlead. A more detailed description of the data collection, composition and analysis methodology is described in **Boxes 1–3** (see also **Tables 1** and **2**).

Unlike many previous studies that reported clinical development success rates for large pharmaceutical companies, this study provides a benchmark for the broader drug development industry by including small public and private biotech companies and specialty pharmaceutical firms. The aim is to incorporate data from a wider range of clinical development organizations, as well as drug modalities and targets. Two landmark publications on the subject, DiMasi *et al.*[6] and Kola *et al.*[8] use 50 and 10 pharmaceutical company pipelines, respectively, to arrive at their conclusions. An important study published by the US Federal Trade Commission Bureau of Economics, Abrantes-Metz *et al.*[9] covered a wide number of drugs over a 14 year period from 1989 to 2002, but did not provide the number or type of companies investigated. Although the impact of company size and experience on R&D productivity has been studied extensively[10–13], success rates established by DiMasi *et al.*[6], Kola *et al.*[8] and Abrantes-Metz *et al.*[9] remain the primary benchmarks for the drug development industry.

We believe it is of great value to report updated success rates that capture the diversity in drug development sponsor types as experience and technology vary widely outside of traditional, large pharmaceutical corporations. Furthermore, the more recent time frame for this study provides insight into the latest industry productivity. A comparison of previously published reports with the current study is summarized in **Table 3** and is discussed below.

One key distinction of the study presented here is our ability to evaluate all of a drug's indications to determine success rates. Danzon *et al.*[12] first considered success rates at the indication level, recognizing that FDA requires clinical trial evidence to establish efficacy for each approved indication. Although these authors included data from 1988 to 2000, an observation period similar to Kola *et al.*[8] and Abrantes-Metz *et al.*[9], their success rates were significantly higher and lacked a characteristic decrease in phase 2 probability reported in previous studies as well as here. Danzon *et al.*[12] concluded that higher clinical development success rates resulted from the analysis of all indications. Even so, evidence presented here strongly suggests that evaluating all indications results in lower probabilities of success across all phases of drug development.

To illustrate the importance of using all indications to determine success rates, consider this scenario. An antibody is developed in four cancer indications, and all four indications transition successfully from phase 1 to phase 3, but three fail in phase 3 and only one succeeds in gaining FDA approval. Many prior studies reported this as 100% success, whereas our study differentiates the results as 25% success for all indications, and 100% success for the lead indication. Considering the cost and time spent on the three failed phase 3 indications, we believe including all 'development paths' more accurately reflects success and R&D productivity in drug development.

Examining individual drug indications allows us to answer the question: "what is the probability that a drug developed for a specific indication will reach approval?" Whereas, using only the lead or most advanced indication seeks to answer the question: "what is the probability that a drug will reach approval for any indication?" This study addresses both questions with emphasis on the findings of the former. In the following sections, we present the results of our analysis as they relate to overall phase success and likelihood of approval (LOA; see **Box 2**), to the type of therapeutic modality, to the disease being treated and to the type of drug application (whether orphan or Special Protocol Assessment (SPA) pathways).

### Phase success and likelihood of approval

We found that approximately one in ten (10.4%, $n$ = 5,820) of all indication development paths in phase 1 were approved by FDA (**Fig. 1** and **Table 4**). Examining the individual phase components of this compound probability, phase I success (the number of phase 1 drugs that successfully transitioned to phase 2 divided by the total transitions in phase 1) was 64.5% ($n$ = 1,918). Success in phase 2 (32.4%, $n$ = 2,268) was substantially lower than in phase 1, but subsequently increased in phase 3 (60.1%, $n$ = 975). The probability of FDA approval after submitting a new drug application (NDA) or biologic license application (BLA) was 83.2% ($n$ = 659).

Success rates for lead indication development paths were higher than for all indication development paths in every phase. Lead indications had a LOA from phase 1 of 15.3% ($n$ = 3,688).

### Success rates by drug classification

Drugs in the BioMedTracker data set were annotated by their FDA classification: new molecular entity (NME), non-NME, biologic and vaccine. However, owing to inconsistency in the FDA classifications, we also used our

## Box 1 Data collection and composition

BioMedTracker, a subscription-based product of Sagient Research Systems (San Diego) introduced in 2002, tracks the clinical development and regulatory history of novel investigational drugs in the United States. Analysts with advanced degrees in the life sciences and medicine maintain the database using information from company press releases, analyst conference calls, and presentations at investor and medical meetings. BioMedTracker also uses other sources, including regular communication with companies conducting clinical trials, to ensure the accuracy and timeliness of the data.

Data included in this study were selected using BioMedTracker's Probability of Technical Success (PTS) calculator, which identified 5,820 phase transitions from January 1, 2003, to December 31, 2011. Transitions in all phases of development were recorded in the early years of observation and resulted from clinical studies initiated before 2003. The data set contained 4,451 drugs from 835 companies and 7,372 independent clinical development paths in 417 unique indications.

The composition of these novel drug development sponsors included a wide range of company sizes and types (**Table 1**). Emerging biotech represented 85% (712) of the companies, whereas a small number (33) of large firms (4% of total) were responsible for 48% (3,573) of indications and 47% (2,075) of drugs in development. Similarly, private firms represented 49% (412) of the companies and fewer than 20% of indications and drugs included in the study.

These ownership classifications were recorded at the end of the analysis time period and underestimate the number of drugs and indications developed by biotech companies due to licensing and acquisitions during the study time frame. In addition, ownership was assigned to the licensee controlling and funding the majority of development. In cases where development and economics were shared equally, ownership was generally assigned to the larger organization, further contributing to the conservative estimate of drugs developed by small and private biotech companies. Although generic products were not included, generic manufacturers developing novel investigational drugs were represented.

The study also likely tracked a larger percentage of late-stage studies as these programs are more often in the public domain. Even so, small biotech companies often disclose ongoing phase 1 studies and we would expect their substantial representation in this study to partially offset the under-representation of early-stage discontinuation rates. Only company sponsored development paths designed for FDA approval were considered; investigator sponsored studies and combinations with other investigational drugs were excluded in this analysis.

In addition, this study analyzed development paths organized by disease area, biochemical composition, molecular size, FDA classification and regulatory status (SPA and orphan drug status). Given the increasing complexity of ownership and diversity of invention in the drug development industry, the study did not further classify the database on the discovery origin or licensing status of the drug.

**Table 1 Analysis of company size and type**

| | Companies | | Indications | | Drugs | |
|---|---|---|---|---|---|---|
| | Number | Percentage | Number | Percentage | Number | Percentage |
| **Company size** | | | | | | |
| Large pharma/biotech (>$5 billion sales) | 33 | 4% | 3,573 | 48% | 2,075 | 47% |
| Small to mid-sized pharma/biotech ($0.1 billion–$5 billion sales) | 90 | 11% | 1,099 | 15% | 724 | 16% |
| Emerging biotech (<$0.1 billion sales) | 712 | 85% | 2,700 | 37% | 1,652 | 37% |
| Total | 835 | – | 7,372 | – | 4,451 | – |
| **Company type** | | | | | | |
| Private | 412 | 49% | 1,269 | 17% | 841 | 19% |
| Public | 423 | 51% | 6,103 | 83% | 3,601 | 81% |
| Total | 835 | – | 7,372 | – | 4,451 | – |

## Box 2 Metrics of success: 'Phase Success' and 'Likelihood of Approval'

There are two different types of success rates reported in this study: 'Phase Success' and 'Likelihood of Approval' (LOA). 'Phase Success' is calculated as the number of drugs that moved from one phase to the next phase divided by the sum of the number of drugs that progressed to the next phase and the number of drugs that were suspended. The *n* value associated with the Phase Success represents the number of drugs that have advanced plus the number of drugs that have been suspended, which we label as phase transitions. For example, if there were 100 drugs in phase 2 development and 50 transitioned to phase 3, 20 were suspended and 30 remained in phase 2 development, the phase 2 Phase Success would be 71.4% (50/70; $n = 70$).

Our second metric, LOA, denotes the probability of reaching FDA approval from the current phase, and is also expressed as a percentage. LOA is calculated as the product of each Phase Success probability leading to FDA approval. The *n* value associated with LOA is the sum of the *n* values for each Phase Success included in the LOA calculation. For example, if a drug is currently in phase 2, and the Phase Success for phase 2 is 30% ($n = 20$), phase 3 is 50% ($n = 10$), and FDA approval is 80% ($n = 5$), then the LOA for the phase 2 drug would be 12% (30% × 50% × 80% = 12%, $n = 35$). This calculation is illustrated in **Supplementary Figure 2**.





data to annotate drugs by their biochemical composition (e.g., peptide, nucleic acid, monoclonal antibody (mAb)) and molecular size (i.e., large and small molecules). For example, FDA often designates large-molecule biologics, such as proteins and peptides, as NMEs. Indeed, large molecules, as defined by the BioMedTracker biochemical categories, comprise 13% of the NME data set, making direct FDA NME to biologic classification comparisons somewhat imprecise. FDA's biologic classification comprises a wider group that includes the Center for Drug Evaluation and Research (CDER) regulated products, such as antibodies, cytokines, growth factors and enzymes, as well as the Center for Biologics Evaluation and Research (CBER) regulated products including blood isolates, gene therapies and cell therapy.

FDA's non-NME classification often includes drugs with the same molecular properties as NMEs, but which are frequently reformulations or combinations of approved products. The majority of non-NMEs also use the 505(b)(2) pathway to gain FDA approval. Vaccines were also treated as a separate class in this analysis, and generic and over-the-counter drugs were not included. A comparative analysis of FDA classifications and BioMedTracker categories can be found in **Supplementary Table 1**. The metrics for the different therapeutic modality types is provided in **Table 4**.

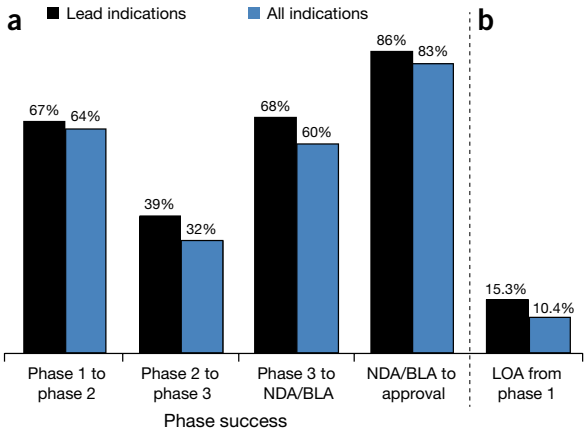


**Figure 1** Phase success and LOA rates. (**a**) Phase success rates for lead and all indications. The rates represent the probability that a drug will successfully advance to the next phase. (**b**) LOA from phase 1 for lead and all indications. Rates denote the probability of FDA approval for drugs in phase 1 development.

NMEs were found to have the lowest success rates in every phase of development; biologics had nearly twice the LOA from phase 1 (14.6%, $n = 1,173$) as NMEs (7.5%, $n = 3,496$) for all indications (**Table 4**). Similar results are seen when the data are reclassified into large-molecule (excluding low molecular weight chemicals and steroids) and small-molecule NMEs: 13.2% ($n = 1,834$) and 7.6% ($n = 3,029$), respectively. In addition, the LOA from phase 1 for mAbs (14.1%, $n = 639$), a good proxy for CDER-regulated biologics, was also consistent with these broader definitions of biologics.

Non-NMEs had the highest LOA from phase 1 of 20.0% ($n = 855$), with success rates well above those of the NME and biologic classifications in every phase. However, many non-NMEs begin development in phase 2 or phase 3, so the actual approval rate is likely higher (assuming that successful phase 1 outcomes would contribute positively to the LOA from phase 1).

When analyzing lead indications only (i.e., on a per drug basis), we find similar rankings for NME, biologic and non-NME, but at much higher success rates. The LOA from phase 1 for biologics and non-NMEs are near one in four and NMEs approach one in eight (12.0%, $n = 2,124$), almost twice what was found when all indications were considered.

### Success rates by disease

We found substantial variation in success rates among disease, as listed in **Table 5** from highest to lowest LOA from phase 1. Oncology drugs had the lowest LOA from phase 1 at 6.7% ($n = 1,803$). Drugs for the 'other' disease group, which combined allergy, gastroenterology, ophthalmology, dermatology, obstetrics-gynecology and urology indications due to small sample size, had the highest LOA from phase 1, at 18.2% ($n = 720$). Drugs for infectious disease and autoimmune-immunology groups had the next two highest LOAs from phase 1, at 16.7% ($n = 537$) and 12.7% ($n = 549$), respectively.

On a lead indication basis, also in **Table 5**, we found that cardiovascular drugs had the lowest LOA from phase 1 at 8.7% ($n = 318$) and the 'other' disease category again had the highest success rate at 24.5% ($n = 499$). The largest difference between lead and all-indication for LOA from phase 1 was observed in oncology: 6.7% ($n = 1,803$) for lead indication and 13.2% ($n = 796$) for all indications. Oncology drugs also had the most nonlead indications (56% of all development paths compared with 28% of non-oncology indications) as a result of the large number of cancers investigated using the same drug. Unfortunately, in oncology, when all indications are considered, only around 1 in 15 drugs entering clinical development in phase 1 achieves FDA approval compared with close to 1 in 8 using the lead indication methodology. As noted above, the result for lead indications represents the most successful development path for a particular compound, thereby addressing LOA on a per drug

## Box 3 Methods used in this study

Data used for this study were extracted from BioMedTracker using a probability of technical success (PTS) tool, which identified all 'Advanced' and 'Suspended' drugs by development phase from January 1, 2003, to December 31, 2011. BioMedTracker tracks the clinical development and regulatory history of investigational drugs to assess its Likelihood of Approval (LOA) from phase 1 by the FDA. The database is populated in near real-time with updated information from press releases, corporate earnings calls, investor and medical meetings, and numerous other sources. These data are recorded in BioMedTracker and tagged with a date.

**Table 2 Definitions of terms used in this study**

| BioMedTracker term | Description for purposes of this study |
|---|---|
| I | Drug is currently in phase 1 |
| I/II, II, IIb | Drug is currently in phase 2 |
| II/III, III | Drug is currently in phase 3 |
| NDA/BLA | Application for approval has been submitted to the FDA and is currently under review |
| Approved, withdrawn from market, approved (Generic competition) | Drug has been approved for marketing in the United States |
| Suspended | Drug is no longer in development |
| Approved in Europe, Approved in other than US/EU, Development, Development outside US | The company developing this drug does not plan to market it in the United States |

Phase is defined as the stage of clinical development in the United States (**Table 2**). Although it is rare, drugs that were removed from development in the United States, but approved in Europe (e.g., vildagliptin for type II diabetes) were considered 'suspended' for the sake of our analysis. In this time period, 7,372 development paths were analyzed, encompassing 4,451 unique compounds. 5,820 unique phase transitions were used to determine the reported success rates. **Table 4** includes the number of observed transitions by phase (a description of the success rate analysis is described). Phase 2 transitions accounted for the highest percentage of the data set with 39% ($n$ = 2,268), compared with 33% in phase 1 ($n$ = 1,918), 17% in phase 3 ($n$ = 975) and 11% in NDA/BLA ($n$ = 659). Nonlead indications comprise 38% ($n$ = 2,132) of the 5,820 total transitions and success rates by phase can be found in **Supplementary Table 2**.

Development paths track a specific indication for each drug. For example, Rituxan (rituximab) in non-Hodgkin's lymphoma qualifies as a development path different from Rituxan in multiple sclerosis (MS). BioMedTracker assigns a unique internal identifier that can be used to isolate all development paths. In addition to tracking the phase of development, BioMedTracker assigns 'lead' status to certain development paths. This is used to denote the most advanced indication in clinical development for a specific drug. Drugs can only have one lead development path, except in specific circumstances where two development paths are being developed simultaneously (e.g., type I and type II diabetes). For example, the Avastin (bevacizumab) colorectal cancer development path was marked as a 'lead' indication, and other Avastin development paths were labeled 'nonlead'. Using this metric, Avastin clinical development can more accurately be viewed as a series of successes and failures, as opposed to simply one success and no failures. However, a drug's lead indication may also change if it fails in development in the lead indication. The lead indication success rate will therefore be higher due to selection bias than the nonlead success rate. This bias does not affect the LOA from phase 1 rate for all indication development paths.

BioMedTracker also records a number of other variables including the following:

- FDA classification (e.g., NME, non-NME, biologic or vaccine)
- Biochemical profile (e.g., small molecule, monoclonal antibody, antisense)
- Disease area (e.g., autoimmune, cardiovascular, oncology)
- Indication (e.g., diabetes, acute coronary syndrome)

In contrast with many earlier studies, which included only a limited sample of drugs from large companies, the current study included BioMedTracker data from small biotech companies as well as specialty and large pharmaceutical firms.

**Phase success and LOA rates calculation.** A common method of determining drug development success rates detailed in DiMasi *et al.*[6] and Abrantes-Metz *et al.*[9] was used in this study. Phase Success, defined as the probability of a drug moving from phase X to phase X + 1, was used as the basis for all analyses. To arrive at this value, the following questions are used to categorize each drug development path: first, was the drug development path ever in phase X? Second, if so, did it advance to phase X + 1? And third, was it 'Suspended'? After categorizing all drug development paths, Phase Success is calculated by dividing the number of development paths that advanced from phase X to phase X + 1 by the sum of the number of development paths that advanced from phase X to phase X + 1 and the number of development paths that were suspended from phase X – Advanced/(Advanced + Suspended) = Phase Success.

Using this method, we arrived at the probabilities of an 'average' drug advancing from phase 1 to phase 2, from phase 2 to phase 3, from phase 3 to filing the NDA/BLA and from filing the NDA/BLA to FDA approval. We then compounded these probabilities to determine the probability (LOA) that a drug in phase X is approved. For example, the LOA for a drug which has entered phase 2 is the product of the phase success rates from phase 2, phase 3 and NDA/BLA. An example calculation is illustrated in **Supplementary Figure 2**.

For purposes of this analysis, all indications that were advanced or suspended in any phase during our collection time frame were included. In practice, this means a drug that 'entered' the analysis in 2003 in phase 2, and later advanced to phase 3, was included in the study. This method was selected because there are relatively few drugs that entered development in phase 1 in the range of years analyzed and have subsequently progressed through final FDA review, and there is less disclosure of drugs in phase 1 development. Abrantes-Metz *et al.*[9] also used a similar method and stated, "We did it this way because the data set has very few drugs with complete information for all… phases." Drugs that remained in the same phase were censored, as were those that moved back a phase but were not suspended[9].

**Table 3 Comparison of our study with previous drug development success rate studies**

| | This study (2013) all indications | | This study (2013) lead indications | | DiMasi *et al.*[6] lead indications | | Kola *et al.*[8] lead indications | | Abrantes-Metz *et al.*[9] lead indications | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Phase success | Phase LOA | Phase success | Phase LOA | Phase success | Phase LOA | Phase success | Phase LOA | Phase success | Phase LOA |
| Phase 1 to phase 2 | 64.5% | 10.4% | 66.5% | 15.3% | 71% | 19% | 68% | 11% | 80.7% | NA |
| Phase 2 to phase 3 | 32.4% | 16.2% | 39.5% | 23.1% | 45% | 27% | 38% | 16% | 57.7% | NA |
| Phase 3 to NDA/BLA | 60.1% | 50.0% | 67.6% | 58.4% | 64% | 60% | 55% | 42% | 56.7% | NA |
| NDA/BLA to approval | 83.2% | 83.2% | 86.4% | 86.4% | 93% | 93% | 77% | 77% | NA | NA |
| LOA from phase 1[a] | | 10.4% | | 15.3% | | 19% | | 11% | 26.4%[c] | NA |
| Number of drugs in sample advanced or suspended[b] | 5,820 | | 4,736 | | 1,316 | | NA | | 2,328 | |
| Dates of source data (duration) | 2003–2011 (9 years) | | | | 1993–2009 (17 years) | | 1991–2000 (10 years) | | 1989–2002 (14 years) | |
| Number of companies | 835 | | | | 50 | | 10 | | NA | |

[a]Probability of FDA approval for drugs in phase 1 development. [b]Total number of transitions used to calculate the success rate (the *n* value noted in the text). [c]Abrantes-Metz, *et al.*[9] reported 26.4% from phase 1 to phase 3. If we were to conservatively apply the 83.2% NDA/BLA success rate found in this study, Abrantes-Metz would yield the highest LOA from phase 1 (21%). NA, data not available.



basis. Using the lead indication methodology to determine success rates, the scope of the challenge in oncology drug development would be dramatically underestimated.

The largest variation in success rates across disease groups was observed in phase 2. In **Table 5** all-indication phase 2 success rates ranged from 26.3% (for cardiovascular) to 45.9% (for infectious disease). In phase 3, all indication success rates ranged from 45.2% (for oncology) to 71.1% (for other). In contrast, phase 1 and NDA/BLA (As only one application, NDA or BLA, will be filed for any single indication, rates are given below for NDA/BLA.) filing success rates were more consistent across disease groups. All indication data from **Table 5** are charted in **Figure 2** to illustrate the large differences in phases 2 and 3 and LOA from phase 1 success rates across disease areas.

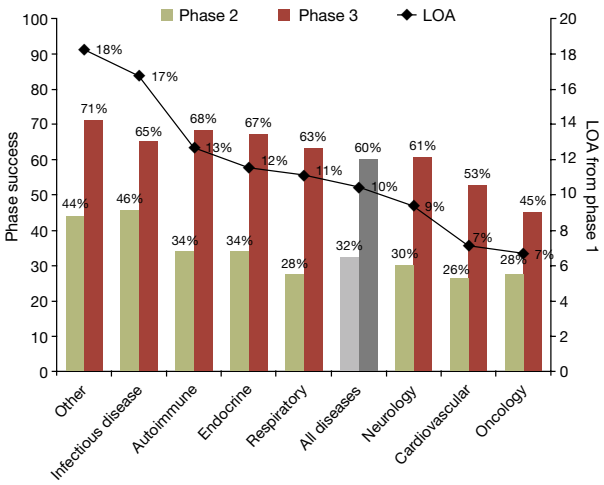


**Figure 2** Phase success and LOA from phase 1 by disease for all indications. The bars represent phase 2 and phase 3 success rates and the line represents LOA from phase 1.

The development paths with the two lowest rates of phase 3 success were oncology and cardiovascular disease, with 45.2% ($n$ = 221) and 52.8% ($n$ = 89), respectively. **Figure 2** also highlights the large step-up in success rates from phase 2 to phase 3 for autoimmune, endocrine and respiratory diseases, increasing from 34% to 68%, 34% to 67%, and 28% to 63%, respectively. The low LOA from phase 1 in oncology rate results primarily from the lack of such a step-up, with a low phase 2 rate of 28.3% ($n$ = 827), followed by a phase 3 success rate of only 45.2% ($n$ = 221).

**Success rates for oncology and non-oncology drugs.** As oncology drugs made up the largest portion of the total data set (31.0% of all transitions) and had the lowest LOA from phase 1 (6.7%, $n$ = 1,803), we investigated their contribution to success rates for the entire data set. To accomplish this, we removed all oncology drug development paths and compared these results to the full data set and oncology development paths alone. **Table 6** shows phase success and LOA rates for drugs for all disease groups, oncology and non-oncology development paths. The LOA from phase 1 across non-oncology indications is nearly twice that for oncology alone, 12.1% ($n$ = 4,017) versus 6.7% ($n$ = 1,803), respectively, reducing the probability of FDA approval in the full data set from nearly one in eight to over one in ten. Interestingly, the LOA from phase 1 for small-molecule NMEs was similar for oncology (6.6%, $n$ = 1,163) and non-oncology (7.9% $n$ = 2,333) indications, and biologics and non-NMEs accounted for much of the difference. For example, oncology biologics had a 7.3% ($n$ = 429) LOA from phase 1 compared with 19.4% ($n$ = 744) for non-oncology biologics.

**Table 7** shows phase success and LOA rates in subcategories of cancer type for oncology drugs. Although a high number of transitions in all phases were seen for the solid tumor ($n$ = 1,358) and hematological ($n$ = 409) subgroups, further classification of oncology indications results in low numbers of transition from phase 3 to NDA/BLA. As is true of the full data set, drugs in phase 2 for oncology subgroups display more transitions and represent the strongest data for specific-indication success rate analysis. Oncology phase 2 success rates ranged from 50.0% ($n$ = 12) in head and neck cancer to 20.9% ($n$ = 24) in prostate cancer; however, the phase 2 rank order by tumor type was uncorrelated with LOA from phase 1 (linear regression, $R^2$ = 0.26). On average, phase 2 success rates were higher in hematological tumors (34.6%, $n$ = 179) than in solid tumors (26.3%, $n$ = 636). Only two phase 3 oncology indications had more than 20 transitions: breast cancer ($n$ = 25) and non–small cell lung cancer ($n$ = 23), which together accounted for ~28% of the solid tumor phase 3 transitions ($n$ = 172). Because of even smaller sample sizes, cancer type success rates were not analyzed by lead indication.

**Success rates for neurology, autoimmune and endocrine disease drugs.** Neurology and autoimmune/immunology disease groups are

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