The Phase 3 Base Rate Worksheet

Historical programs, not a forecast for your drug

The study estimates that **59.0%** of industry-sponsored development paths reaching Phase 3 in 2000-2015 advanced to regulatory approval; the estimated non-approval share is **41.0%**. Across the nine therapeutic groups below, rates ranged from 35.5% to 85.4%.

1. Find the therapeutic group

Therapeutic group	Approved	SE (pp)	Paths
Vaccines (infectious disease)	85.4%	1.4	609
Infectious disease	75.3%	1.3	1,078
Ophthalmology	74.9%	3.0	207
Genitourinary	66.5%	3.2	212
Autoimmune / Inflammation	63.7%	1.5	969
Cardiovascular	62.2%	1.6	964
Metabolic / Endocrinology	51.6%	1.5	1,101
CNS	51.1%	1.5	1,156
Oncology	35.5%	1.4	1,236
All indications	59.0%	0.6	7,532

Source: Wong, Siah and Lo (2019), Table 2. Global industry-sponsored programs, January 1, 2000 to October 31, 2015. Paths are reconstructed within drug, indication and sponsor combinations, including imputed transitions and time-based termination classifications. The nine group counts sum to 7,532. SE means standard error, in percentage points.

The smaller ophthalmology and genitourinary samples have wider uncertainty. Compare the rate and its standard error before treating it as a precise estimate. A larger SE means less precision; there is no universal SE cutoff that makes a rate unusable.

Compare the dataset before the rate

2. Global and FDA-only samples

Question	Wong, Siah & Lo	BIO / Informa / QLS
All indications	59.0%	52.4%
Oncology	35.5%	43.9%
Window	2000-2015	2011-2020
Regulator	Global	FDA only
Method	Path-by-path	Phase-by-phase
Counting unit	Drug/indication/sponsor path	Registration program

BIO reports 57.8% for Phase 3 to filing and 90.6% for filing to approval. Their product is 52.4% after rounding. That dataset covers 12,728 transitions from 9,704 company-sponsored FDA registration-enabling programs at 1,779 companies, January 1, 2011 to November 30, 2020.

The FDA-only sample is lower overall and higher in oncology. Neither result corrects the other: the samples, windows, counting units and methods differ. Name the dataset you use and do not average them.

3. What the numbers cannot establish

Not FDA-specific. Wong measures regulatory approval across global sources, not the probability of a particular FDA decision.

Not your drug's probability. Trial design, endpoint, comparator, manufacturing record and review history are not represented by a therapeutic-group average.

Paths, not unique drugs. A compound can contribute several paths across indications or sponsors. Missing transitions and a 900-day Phase 3 termination rule affect the reconstructed outcomes.

A historical window. The sample ends in 2015. Pathways, sponsor mix and the review environment have changed. A newer rounded Citeline estimate is contextual evidence, not a replacement value for this sample.

Six checks before a decision date

Company / ticker: _____ Indication: _____

Decision / readout date: _____ Dataset used: _____

1. Find the indication, not just the drug.

Read the Conditions field in the Phase 3 ClinicalTrials.gov record or the company pipeline. Match that indication to a table row.

Your note: _____

2. Read the rate and its standard error.

Record both. A wider standard error and smaller path count call for more caution about precision.

Your note: _____

3. First review or resubmission?

A program returning after a complete response letter differs from an initial submission; the historical rate does not separate them.

Your note: _____

4. What deficiency, if one is known?

A manufacturing or labeling problem differs from a request for another trial. Do not infer the deficiency from the label alone.

Your note: _____

5. What would a delay cost in cash?

Check cash runway and financing needs. Wong section 4.5 reports terminated Phase 3 trials lasted about 3.2 months longer than advanced trials; this is a sample comparison, not a forecast of your review delay.

Your note: _____

6. Could one bad outcome force a sale?

Write a position limit that fits the rest of your portfolio. This worksheet supplies no target allocation or return forecast.

Your note: _____

No expected-return shortcut: Do not multiply a regulatory approval rate by Hwang's event-study medians. They concern different events and samples. Hwang's 0.8% / -2.0% are CAR(-2,0) medians for clinical-result announcements, not single-day FDA-decision returns.

Sources: Wong et al., Biostatistics 20(2):273-286, DOI 10.1093/biostatistics/kxx069; BIO / Informa / QLS (2021), Clinical Development Success Rates 2011-2020; Hwang (2013), DOI 10.1371/journal.pone.0071966.