Of the drug programs that reached Phase 3 between 2000 and 2015, **59.0% went on to win regulatory approval**. The other 41.0% did not. The rate swings from 35.5% to 85.4% depending on the disease. Find your holding's row before the decision date, not after.

1. PHASE 3 TO APPROVAL, BY THERAPEUTIC GROUP

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

Source: Wong, Siah and Lo (2019), *Biostatistics* 20(2):273-286, Table 2. Global industry-sponsored programs, 1 Jan 2000 to 31 Oct 2015. SE is the standard error. Rows with SE at or above 3.0 rest on roughly two hundred observations and should be read as a direction rather than a figure.

2. THE SAME QUESTION, A DIFFERENT DATASET

Phase 3 to approval	Wong, Siah & Lo	BIO / Informa / QLS
All indications	**59.0%**	**52.4%**
Oncology	**35.5%**	**43.9%**
Window	2000 to 2015	2011 to 2020
Regulator	Global	FDA only
Method	Path-by-path	Phase-by-phase
Counting unit	Drug and disease path	Registration program

Read the oncology row twice. The FDA-only dataset is lower overall and *higher* on oncology, 43.9% against 35.5%. Both numbers are correctly copied from their sources. They disagree because the samples, windows, counting units and arithmetic all differ. A base rate is a fact about a dataset, not about your drug. Name which one you are quoting, and never average them.

3. SIX CHECKS BEFORE A DECISION DATE

	CHECK	YOUR ANSWER
1	**Find the indication, not the drug.** ClinicalTrials.gov, Conditions field on the Phase 3 record, or the Indication column of the company pipeline page. That phrase maps to a row in section 1.	
2	**Read the row, then read its standard error.** SE at or above 10 means direction, not number.	
3	**First review or resubmission?** A program returning after a complete response letter sits in a different position. The base rate does not separate the two.	
4	**What kind of deficiency, if one is known?** A labelling or manufacturing fix and a demand for another trial are both complete response letters. They are not the same event for a shareholder.	
5	**What does a delay cost in cash?** Terminated Phase 3 trials concluded about 3.2 months after advanced ones. A program running long is not the reassurance it reads like.	

	CHECK	YOUR ANSWER
6	**Size the position to one bad morning.** No target percentage exists. The test is whether one decision going against you would force a decision you do not want to make.	

4. WHAT THESE NUMBERS DO NOT TELL YOU

It is regulatory approval, not FDA approval. Wong, Siah and Lo drew on data covering United States and non-United States sources.

It is a category history, not your drug's probability. 35.5% is what happened to 1,236 oncology programs. Your drug's trial design, endpoint, comparator and manufacturing record are not in the table.

The unit is a path, not a drug. One drug aimed at one disease. A compound tested against three diseases appears three times.

The window closed in 2015. Accelerated pathways and the review environment have moved since. A newer Citeline analysis covering 2014 to 2023 puts overall Phase 1 to approval at 6.7%.

One calculation this worksheet deliberately does not do. Approval rates and published announcement returns are not combined here into an expected portfolio drag. They measure different events on different samples, and a probability-weighted blend of two conditional medians is not an expected value.

SOURCES

Wong C.H., Siah K.W., Lo A.W. (2019). Estimation of clinical trial success rates and related parameters. *Biostatistics* 20(2):273-286. doi:10.1093/biostatistics/kxx069. Corrigendum 20(2):366.

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