

Hay, M., *et al.* (2014)

## SUPPLEMENTARY MATERIALS

**Table S1 Comparison of FDA classifications and BioMedTracker biochemical categorizes.** Number of drugs FDA classified as NME, Biologic, or Non-NME compared with BioMedTracker's biochemical property designations.

BMT Biochemical Category	FDA Classification			
	NME	Biologic	Non-NME	Vaccine
Small Molecule (peptide, steroid, etc.)	4055	24	977	5
Protein, Non-Antibody	71	537	18	4
Protein, Antibody	0	758	0	1
Nucleic acid - RNA targeted	190	11	3	3
Nucleic acid - DNA targeted	0	54	0	0
Vaccine	0	9	0	303
Other	118	78	30	2

**Table S2 Phase Success and LOA for lead and non-lead indications.** Due to selection bias, non-lead indication success rates have a much lower success rate across all phases.

	PI to PII				PII to PIII				PIII to NDA/BLA				NDA/BLA to Approval			
	Total in Phase	Advanced or Suspended	Phase Success	Phase LOA	Total in Phase	Advanced or Suspended	Phase Success	Phase LOA	Total in Phase	Advanced or Suspended	Phase Success	Phase LOA	Total in Phase	Advanced or Suspended	Phase Success	Phase LOA
All	2541	1918	64.5%	10.4%	3743	2268	32.4%	16.2%	1554	975	60.1%	50.0%	908	659	83.2%	83.2%
Lead	1770	1336	66.5%	15.3%	2070	1247	39.5%	23.1%	1009	633	67.6%	58.4%	664	472	86.4%	86.4%
Non-Lead	771	582	59.8%	4.9%	1673	1021	23.8%	8.2%	545	342	46.2%	34.6%	244	187	74.9%	74.9%

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Figure S1 Average time (months) from first review CRL to approval.

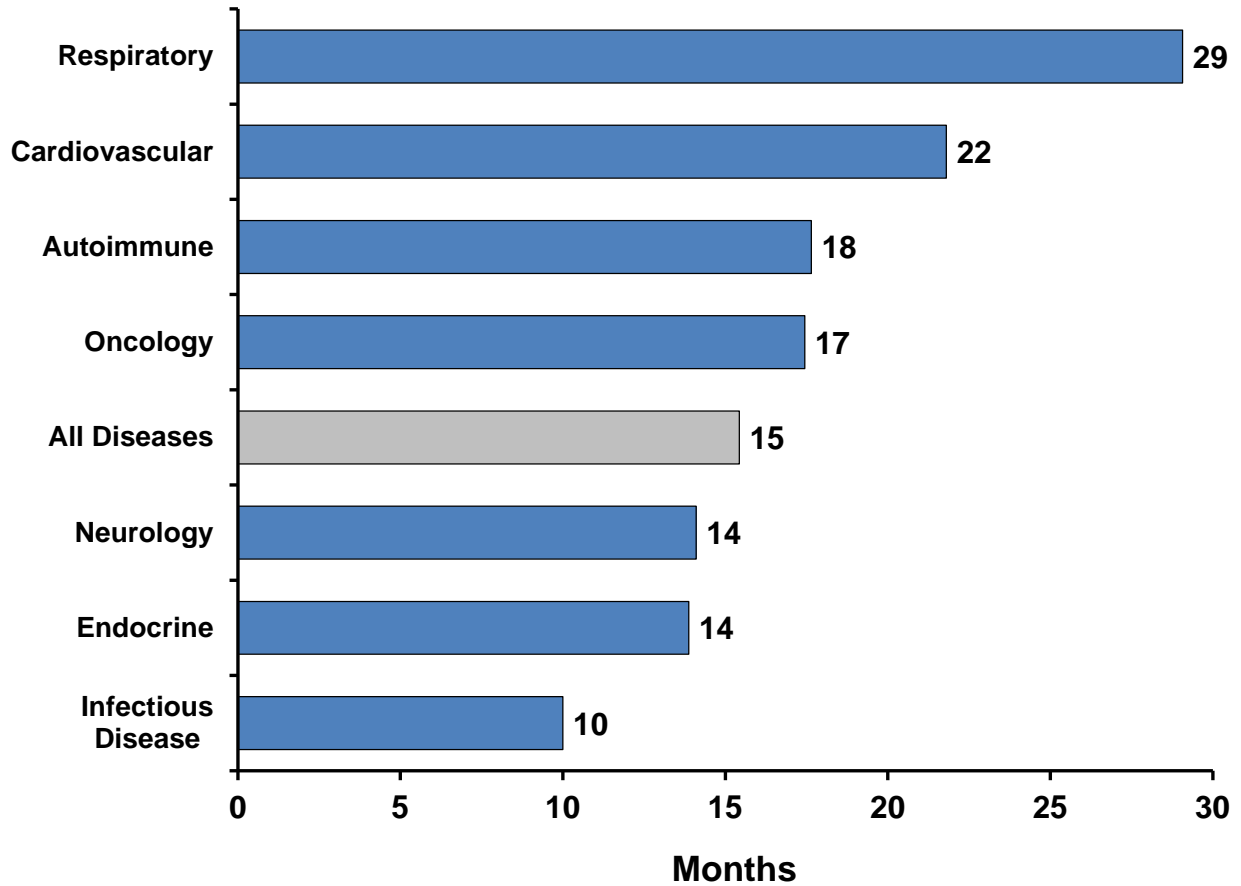


Figure S2 Example calculation for LOA from Phase I. Likelihood of Approval (LOA) denotes the probability of reaching FDA approval from the current phase, and is expressed as a percentage. LOA is the product of each phase success probability leading to FDA approval.

Phase Transition	Phase Success	LOA
P1 to P2	64.5%	10.4%
P2 to P3	32.4%	16.2%
P3 to NDA/BLA	60.1%	50.0%
NDA/BLA to Approval	83.2%	83.2%

$$.645 \times .324 \times .601 \times .832 = .104$$