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SUPPLEMENTARY INFORMATION

In format as provided by the authors

Trends in clinical success rates and therapeutic focus

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Supplementary information | Data and analysis methods

CMR International operates a consortium of innovative biopharmaceutical companies to measure and compare R&D performance on a like-for-like basis. This consortium includes ~30 large, mid-sized and small companies, collectively representing ~80% of the top 20 biopharmaceutical companies by global R&D expenditure. The CMR R&D Performance Metrics dataset comprises performance data for consortium members and includes details of pipeline progressions and terminations. The progression decision methodology (PDM) assesses the fate of active substances exiting a phase within a specified year range (such as 2015–2017), and assigns a fate as 'progressed' or 'terminated' (active substances remaining in-phase are not considered within the PDM). These values can then be used to calculate a probability of success to market.

The data for Figure 1a on probability of success (%) between different stages in 3-year time periods are based on analysis of the following number of projects in this dataset:

	2010–2012 (*n*)	**2011–2013 (*n*)**	**2012–2014 (*n*)**	**2013–2015 (*n*)**	**2014–2016 (*n*)**	**2015–2017 (*n*)**
Phase III to launch	49% (184, 102)	54% (174, 119)	57% (188,129)	63% (194, 137)	61% (218, 128)	62% (197, 129)
Phase II to phase III	23% (420)	22% (411)	24% (383)	22% (386)	24% (352)	25% (301)
Phase II to launch	11% (420, 184, 102)	12% (411, 174, 119)	14% (383, 188,129)	14% (386, 194, 137)	15% (352, 218, 128)	15% (301, 197, 129)
Phase I to launch	6% (631, 420, 184, 102)	6% (585, 411, 174, 119)	7% (589, 383, 188,129)	7% (566, 386, 194, 137)	7% (547, 352, 218, 128)	7% (478, 301, 197, 129)

The success rates for composite phases such as phase III to launch are arrived at by multiplying the individual phase success rates together, and the values of *n* for each phase are shown separately. For example, during 2010–2012, the *n* for phase III to submission is 184 and the *n* for submission to launch is 102.

The data for Figure 1c on late-stage development (phase III to launch) success rates (%) for rare or non-rare diseases are based on analysis of the following numbers of projects in this dataset. Rare diseases were defined as conditions that affects fewer than 200,000 people in the United States, and include both oncology and non-oncology indications.

	2010–2012 (*n*)	**2011–2013 (*n*)**	**2012–2014 (*n*)**	**2013–2015 (*n*)**	**2014–2016 (*n*)**	**2015–2017 (*n*)**
Rare	50 (18, 11)	40 (24, 15)	46 (29, 23)	52 (38, 26)	53 (48, 28)	61 (49, 30)
Non-rare	49 (166, 91)	56 (150, 104)	59 (159, 106)	67 (156, 111)	64 (170, 100)	63 (148, 99)

The success rates for phase III to launch are arrived at by multiplying the individual phase success rates (for phase III to submission and submission to launch) together, and the values of *n* for each phase are shown separately.

The data for Figure 2 on probability of launch by therapeutic area over time were sourced from the CMR Performance Metrics dataset (2010–2017) and are based on analysis of the following numbers of projects.

	Phase I *n*	**Phase II *n***	**Phase III *n***	**Submission *n***
Alimentary and metabolism	133	88	45	33
Cardiovascular	73	42	22	13
Anti-infectives	103	78	40	38
Musculoskeletal	84	47	16	12
Nervous system	198	112	29	17
Respiratory	107	78	21	16
Anticancer	247	126	76	61

The data for Figure 3 on the percentage of new drug approvals sponsored by major biopharmaceutical companies 2010-2018 are based on approvals sourced from the FDA website. Major biopharmaceutical companies were defined as the top 20 biopharmaceutical companies based on 2017 pharmaceutical revenues sourced from Cortellis Competitive Intelligence.