Evaluate Vantage

May 23, 2022

Diagnostics beat implants in the race to market

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Roche had the most innovative approvals over the last five years – but took second place in terms of speed.

Diagnostics companies have a sizeable advantage over developers of other forms of medical devices in that their products achieve approval in a much shorter time frame. An analysis of the number and speed of FDA approvals of innovative medical technologies over the last five years puts the test makers Roche and Qiagen way out in front; makers of complicated hospital equipment and heart implants, like Asahi Kasei and Abbott, lag behind.

But a look at the development strategies used by these companies – whether they tend to develop their products in house or obtain them via company acquisitions – gives a less clear-cut picture. In some cases internal R&D was rewarded with swift approvals, whereas some of the groups benefited from prioritising M&A.

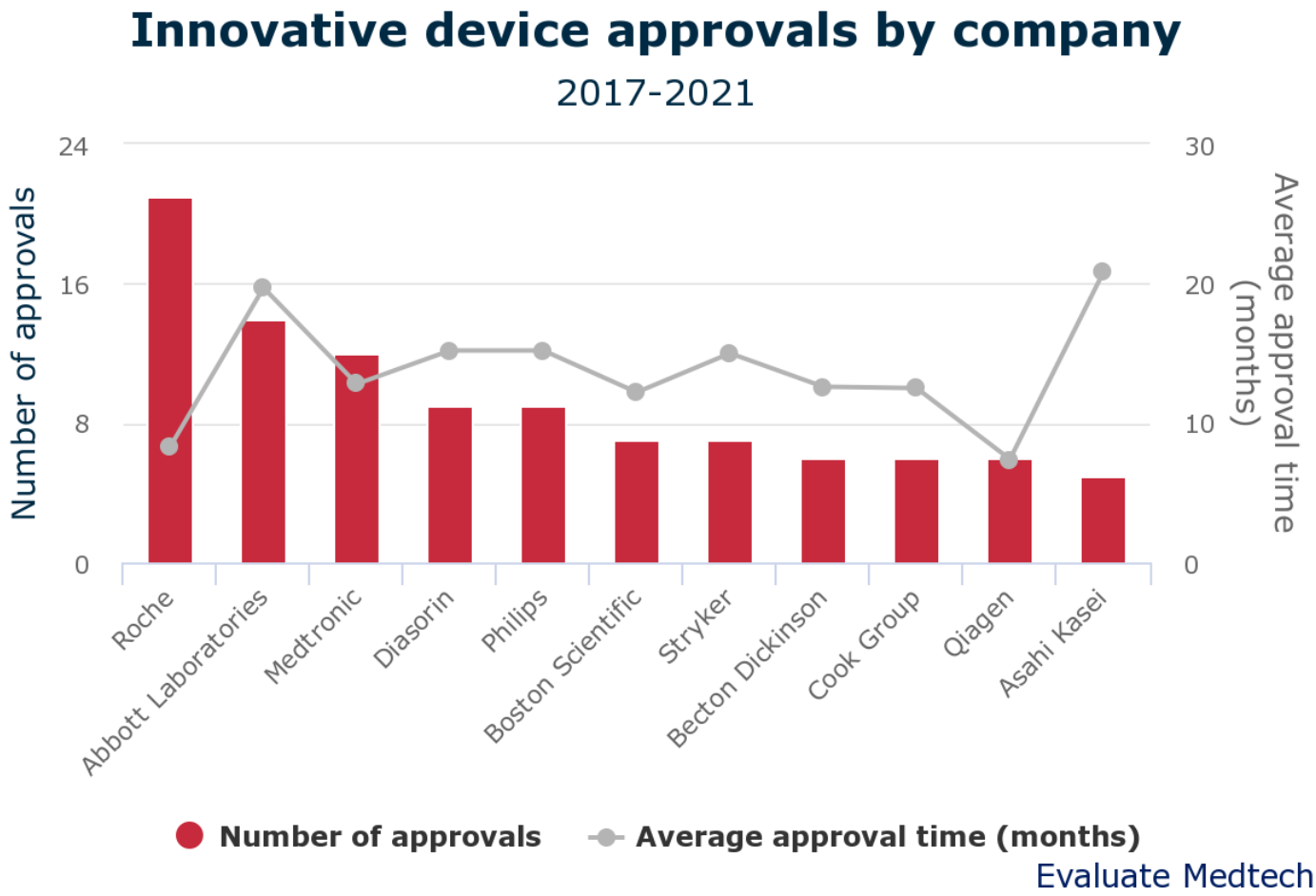
The analysis below considers the companies that received at least five FDA first-time premarket approvals, humanitarian device exemptions or de novo 510(k) clearances between the start of 2017 and the end of last year. These regulatory paths are used for medical technologies unlike anything already on the market – products that represent true advances.

Roche leads the way in terms of the number of these approvals, with 21 – all for in vitro diagnostics. All were either tests to aid cancer treatment – including liquid biopsies – or for infectious disease. These being relatively simple, non-invasive products, they are easily evaluated for approvability, and Roche's products were greenlit in a mean of just 8.3 months.

The winner

But another company was faster still. Qiagen's tests, mostly designed for tumour profiling but also including a test to predict the risk of preterm birth, were approved in an average of 7.4 months.

It should be noted that, though both Qiagen and Roche were heavily involved in Covid test development, the figures for these companies do not incorporate any Covid tests; these reached market via the emergency authorisation pathway and do not appear in this analysis.



Of course, diagnostics makers can bypass the FDA if they wish, marketing their tests via Clia waiver rather than seeking formal approval. Most diagnostics groups make use of the Clia pathway, so arguably this analysis does not give a complete picture of how quickly these companies' products go on sale.

All the tests for which Qiagen did receive FDA approval over the past five years, and all but one of Roche's, were developed organically from internal R&D efforts. The other pure-play diagnostics company in the cohort, Diasorin, also worked entirely in-house.

Among more traditional medtech companies strategies diverge – and so do the results.

Of the 10 companies in this cohort, Becton Dickinson is by far the keenest on buying in innovation. Many of its approved products came via the acquisition of CR Bard in 2017, including the Covera and Venovo stents. The purchase of Lutonix supplied the drug-coated angioplasty balloon of the same name.

The approach seems to be working. The devices it bought were evaluated and approved by the FDA an average of six months faster than the products BD developed in house.

Innovative device approvals 2017-21 by company strategy			
Company	**% developed in-house**	**Ave approval time in-house (months)**	**Ave approval time bought in (months)**
Becton Dickinson	17%	17.7	11.6
Philips	78%	17.5	7.3
Asahi Kasei	80%	7.4	18.5
Medtronic	83%	12.3	15.3
Abbott Laboratories	86%	11.8	67.6*
Boston Scientific	86%	12.9	8.4
Stryker	86%	15.3	13.0
Roche	95%	8.0	6.0
Cook Group	100%	12.5	-
Diasorin	100%	15.2	-
Qiagen	100%	7.4	-
Average		12.5	19
**Abbott time is skewed by one outlier: the Amplatzer Post-Infarct Muscular VSD Occluder took nearly 10 years to be approved. Source: Evaluate Medtech.*			

To be considered bought in, a device's regulatory submission must have been made by a company that was subsequently bought by the recipient of the approval.

In fact, for most of these groups, the products that came via acquisitions completed FDA review more swiftly than those developed internally. With dealmaking seemingly largely off the table this year, medtechs could soon find themselves waiting longer for their approvals.