

It's official: "pipeline in a product" is a thing



[Edwin Elmhirst](#)



Big pharma pipelines are getting smaller, but novel medicines are being tested in more indications than ever before, a new analysis finds.

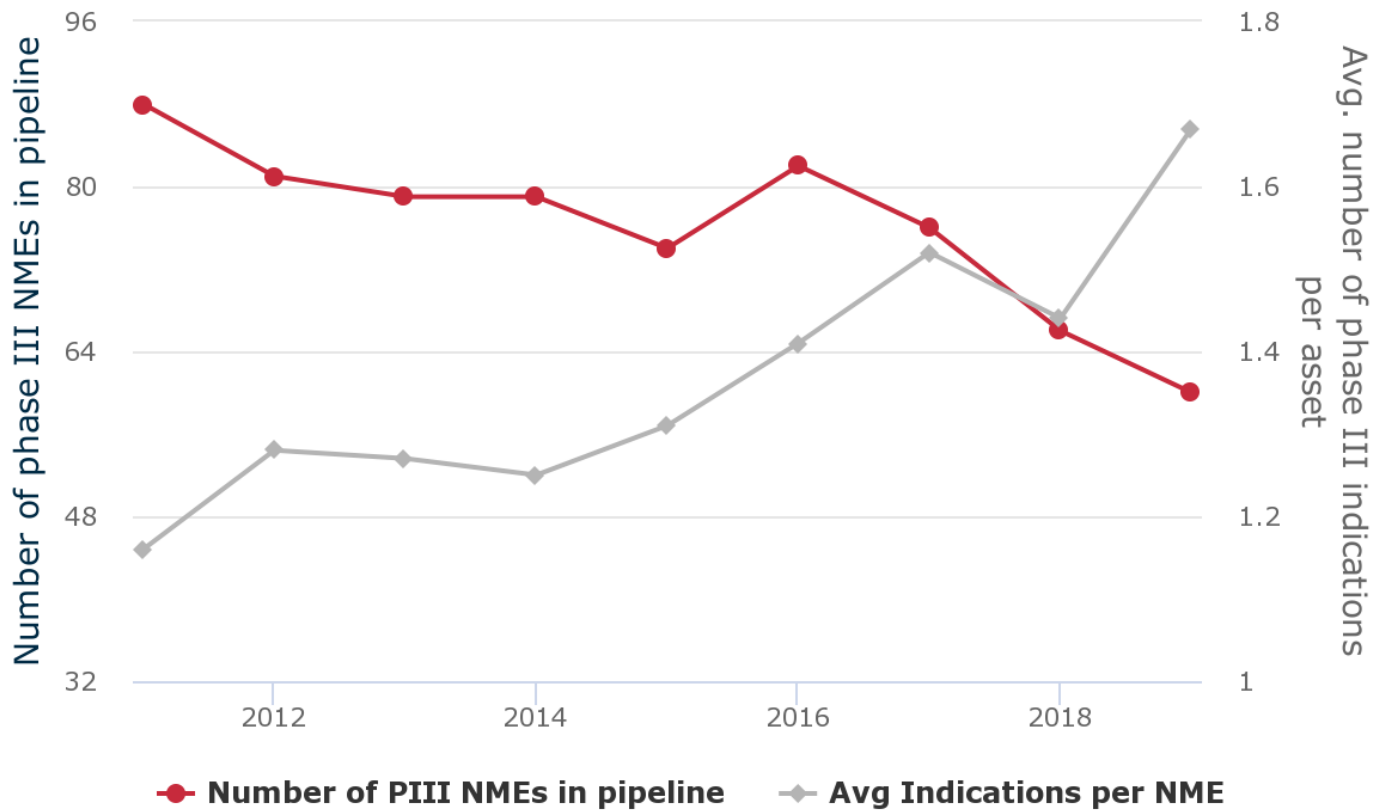
The number of novel, pivotal-stage projects in big pharma pipelines has noticeably dropped over the past couple of years, a recent *Evaluate Vantage* analysis found ([Big pharma sports smallest late-stage pipeline for a decade, June 17, 2020](#)). This raises a question: is this happening because developers are investing more in their success stories, and pursuing the so-called "pipeline in a project" approach?

This seems to be partly true, a new crunch of the data suggests. Since 2014 there has been a clear rise in the average number of indications in which novel products are being tested. This has largely been driven by the arrival of immuno-oncology, and the huge brand extension programmes conducted with checkpoint inhibitors, but the same trend is visible elsewhere too.

The chart below shows that big pharma pipelines really started shrinking around the same time as I-O took off. And this trend is not simply a feature of fewer trials being started. The world's 11 largest drug makers started 2,243 phase III trials of new molecular entities (NMEs) in 2019, by *Vantage's* calculations, a figure only 4% lower than in 2011.

Over the same time, though, the number of novel projects sitting in these developers' phase III pipelines dropped 32%. This was calculated by using historical pipeline data from *EvaluatePharma*, with a count conducted in April of every year.

Big Pharma's phase III NME pipeline



Evaluate

For the analysis of the number of average indications per NME, *Vantage* collected all phase III trial starts for projects – whether already marketed or still in R&D – each year. A big pharma company had to be listed as primary sponsor. The number of separate indications that each product was being tested in, in terms of trials initiated each year, was also found.

This allowed the average number of indications per product to be calculated each year, across the entirety of big pharma's phase III clinical efforts.

The outcome: in 2019 on average an NME was being tested in 1.7 indications, up from 1.2 in 2011. This might not seem like a big rise in absolute terms, but it equates to a 44% increase.

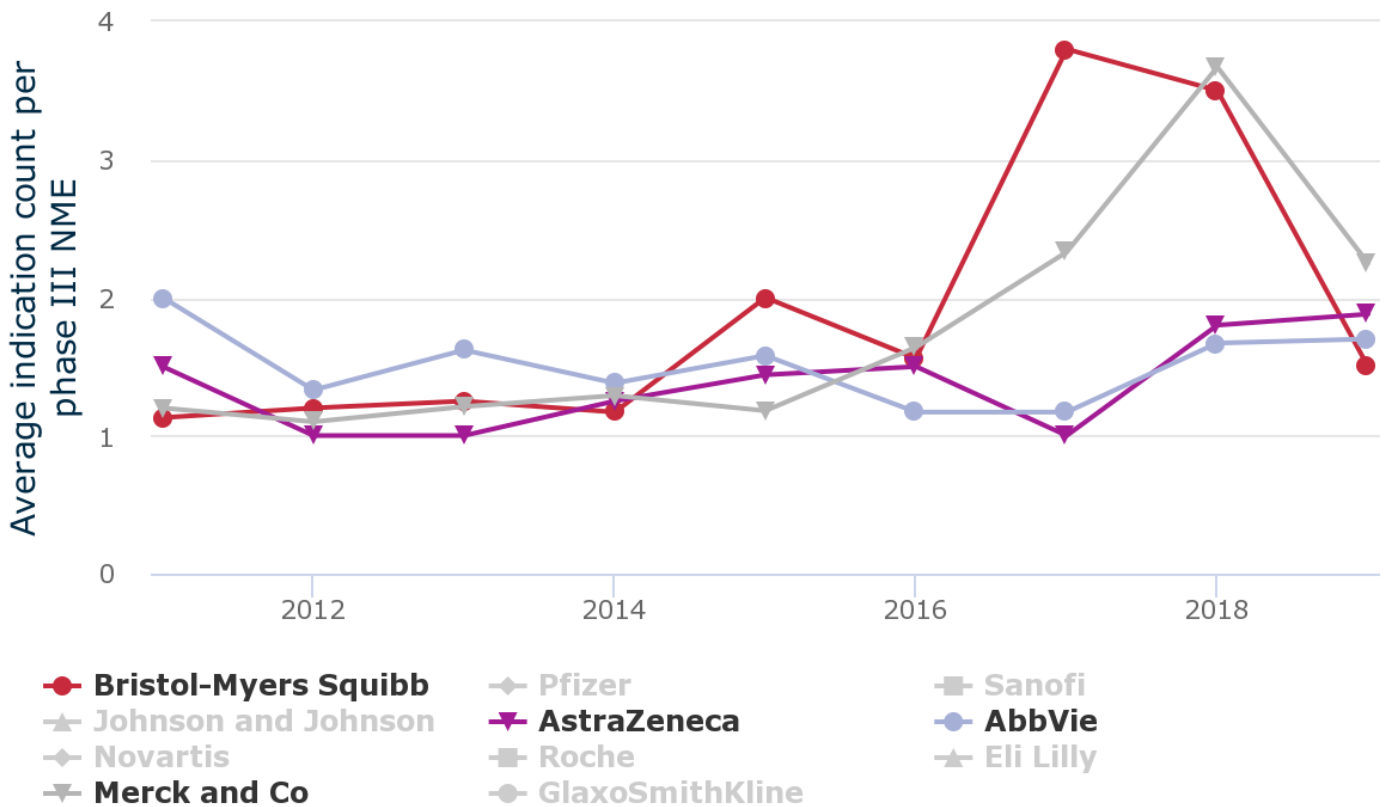
A look at all this on a company level, below, highlights how two groups – and indeed two products – have largely driven this trend. Merck & Co's Keytruda and Bristol Myers Squibb's Opdivo have been put through huge clinical programmes, with AstraZeneca's Imfinzi and Roche's Tecentriq also being trialled very widely.

Merck's Keytruda investment will surely break records. In 2015, for example, 14 phase III trials were started with the checkpoint inhibitor, in nine different tumour types.

The PD-(L)1 inhibitors are not entirely responsible for this tightening of focus. The rise of immunotherapies for diseases like rheumatoid arthritis, Crohn's disease and psoriasis has also seen the same drug being tested in numerous settings. Abbvie's Humira and Novartis's Cosentyx feature prominently in this realm.

As a result, it is the dominant I-O companies and those with an autoimmune focus that are on an upward trend in the chart below.

Phase III indications per NME



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This analysis supports the theory that phase III pipelines are shrinking because more attention is being directed at fewer projects. Whether this strategy pays off is another question entirely, and of course there will always be winners and losers; in I-O, Merck has left other contenders in its dust.

And of course this is not to suggest that big pharma does not need to beef up its late-stage pipelines. Several large drug makers are under pressure to do just this, to diversify away from these hugely successful products that have sucked up so much energy. Abbvie, for example, has been criticised for its reliance on Humira, and Merck is already close to replicating this scenario with Keytruda.