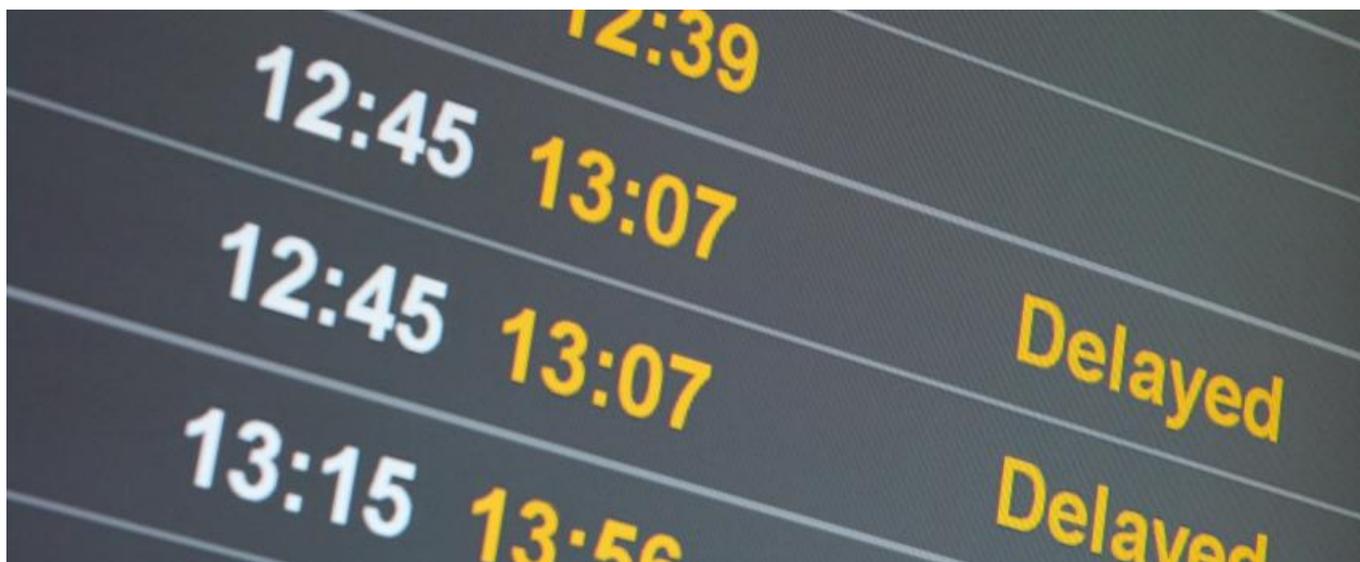


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Clinical trial delays become reality as Covid-19 risk spreads



[Jacob Plieth](#)



A Vantage analysis identifies 315 pivotal trials that, like Lexicon's Scored and Soloist studies, risk never being completed.

As the knock-on effect of Covid-19 spreads far and wide, one aspect biopharma investors must consider is the risk that ongoing trials might be delayed or even abandoned. Yesterday Lexicon provided a case in point, cancelling two Zynquista studies that had recently completed enrolment of nearly 15,000 type 2 diabetics.

True, the coronavirus pandemic was only one reason cited, and it is likely that Lexicon largely wanted to end uncertainty and accept that a partner to fund the trials to completion would not be found. But *Vantage* has identified a further 315 pivotal studies due to end this year, in 172,104 subjects, that might suffer a similar fate.

Among these feature such projects as Pfizer's *Clostridium difficile* vaccine candidate PF-06425090, whose [Clover study](#) is, with 17,525 subjects enrolled, the biggest in this analysis. A [separate PF-06425090 trial](#), seeking to recruit 1,960, features among the top five studies reading out this year that have yet to enrol fully.

Under threat

A huge amount of clinical work is under threat, and this analysis sought to identify biopharma's most advanced, and most valuable, crop of R&D assets.

To pinpoint studies with the most invested – in terms of time and money – *Vantage* searched specifically for pivotal-stage projects that have yet to receive US approval, in trials that have a 2020 primary completion date, according to [clinicaltrials.gov](#).

The topline analysis reveals 168 trials still recruiting, and another 147 that are active but fully enrolled, comprising 64,856 and 107,248 subjects respectively. Remarkably, it looks like at least five near-term blockbusters are under threat: Lilly's tirzepatide, Reata's bardoxolone, Immunomedics' sacituzumab govitecan, Bristol-Myers Squibb's Tyk2 inhibitor and Galapagos's filgotinib.

The exposure of Bristol is especially striking: four Tyk2 studies are due to be completed this year, plus another four of ozanimod. The latter project features in the contingent value right issued under the Celgene acquisition; [as Stat News has pointed out](#), FDA review delays could mean that this CVR never pays out.

Blockbusters under threat? Projects in this analysis with biggest projected sales potential

Project	Company	2024e sales (\$m)	Trial under threat?
Tirzepatide	Lilly	1,619	NCT03882970
Bardoxolone methyl	Reata	1,608	NCT02657356
Sacituzumab govitecan	Immunomedics	1,365	NCT02574455
BMS-986165 (Tyk2)	Bristol-Myers Squibb	1,178	NCT03611751; NCT03624127; NCT04167462; NCT03924427
Filgotinib	Gilead	1,031	NCT02914522
Ozanimod	Bristol-Myers Squibb	966	NCT02576717; NCT02435992; NCT03440372; NCT03440385
Efgartigimod	Argenx	964	NCT03669588
Mirikizumab	Lilly	848	NCT03535194; NCT03518086
AXS-05	Axsome	753	NCT02741791; NCT04039022
Fintepla	Zogenix	694	NCT03355209; NCT02682927; NCT02826863

Source: clinicaltrials.gov & EvaluatePharma sellside consensus.

There are numerous ways in which the Covid-19 situation can hit a clinical trial. A big risk is that patients are lost to follow-up; early analysis is possible, but would require a protocol change. If a database has been locked the problem is less severe, but the actual analysis could be delayed at the CRO.

Already, outside the pivotal setting, many of the first quarter's expected clinical readouts are in doubt, and Provention Bio, Iveric Bio and Arrowhead are three companies that have recently said they would pause study recruitment ([Will pending clinical readouts make it across the line?](#), March 18, 2020).

In Lexicon's case the pointlessness of the [Scored and Soloist trials, halted yesterday](#), was perhaps a foregone conclusion. Zynquista is awaiting approval for type 1 diabetes, and the type 2 setting of Scored and Soloist was meant to have opened up its really big market.

However, Lexicon lost Sanofi as a partner, and completing the two trials relied on it finding a new licensee - something that, with the pandemic situation imposing severe restrictions on meetings and the movement of people, must have been seen as impossible.

It is fortunate for sponsors that the US FDA has taken a lead on the problem of trial delays, [spelling out its willingness](#) to consider protocol amendments, design changes and alternative methods of study subject assessment. This could be a small mercy, but it is something.

Big phase III trials that are still searching for patients, but should be getting close*

Project (setting)	Company	Enrolment	Trial ID
PT027 (asthma)	Astrazeneca	3,100	NCT03769090
PF-06425090 (<i>C difficile</i> -associated diarrhoea)	Pfizer	1,960	NCT03918629
Mirikizumab (ulcerative colitis)	Lilly	1,160	NCT03518086
STS101 (migraine)	Satsuma Biotech	1,140	NCT03901482
Vibegron (overactive bladder)	Urovant	1,088	NCT03902080

*Assumes that primary completion date is accurate. Source: clinicaltrials.gov.

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