

Early-stage US clinical holds spread



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It might be going too far to suggest that the recent spate of clinical holds is evidence of the FDA suddenly getting tough, but the fact that all of these concern very early-stage projects should give pause. The agency today put on hold a phase 1 X-linked adrenoleukodystrophy trial of Viking's VK0214, after stymying no fewer than three IND applications, from Denali, Dyne and Yumanity, over the previous 10 days. And neither do these holds affect cutting-edge [gene therapies, which have faced their own toxicity questions](#); the four assets in question comprise two small molecules, an antibody and a morpholino oligomer (two of these are using a TfR1-based transporter). At least Viking's setback appears to be the result of a technicality; the FDA recently designated VL0214's phase 1 trial a phase 2, something that requires a rodent genotoxicity study to be carried out first, Viking says. And it has not been all bad news of late: the FDA this month lifted two clinical holds, one on Spero's nontuberculous mycobacterial disease project SPR720 and the other on Allogene's entire pipeline. The Spero hold had been in place for 11 months, but [Allogene's took just three months to resolve](#).

Selected US clinical holds

Hold issued	Hold announced	Company	Project	Status/detail	Company timeline
ND	24 Jan	Viking	VK0214	Ph1 (now ph2) X-linked adrenoleukodystrophy trial on hold; rodent genotoxicity trial needed	Expects to fulfil request Q2 2022
ND	19 Jan	Yumanity	YTX-7739	Preclinical (IND application on hold for multiple dosing in Parkinson's disease)	None (no official hold letter yet)
14 Jan	18 Jan	Dyne	DYNE-251	Preclinical (IND application on hold for exon 51 skipper in Duchenne muscular dystrophy; more preclinical & clinical data requested)	Expects to fulfil request Q2 2022
12 Jan	13 Jan	Denali	DNL919	Preclinical (IND application on hold for anti-Trem 2 MAb in Alzheimer's)	None (no official hold letter yet)

Source: company announcements. ND=not disclosed.

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