Evaluate Vantage

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Regulators: Covid-19 vaccines need animal data, but not always up front

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Global regulators got together this week to figure out acceptable levels of preclinical data to justify moving a novel coronavirus vaccine very quickly into human testing, and the answer seems to be: it depends. Information on closely related projects and well-characterised platform technologies can support a swift initiation of clinical work, though developers need to provide a data-backed rationale to justify why certain preclinical work need not be completed first. The working group, co-chaired by the EMA and FDA, stated animal data would be required, and the immune response characterised, although efficacy in animal challenge models need not be demonstrated before human studies commence. This preclinical work can be conducted in parallel in certain cases, but risk-mitigation strategies must be in place; the potential for vaccine-induced disease enhancement is a particular concern. A lack of suitable animal models means that requiring preclinical work to be completed before starting trials would significantly delay clinical vaccine development, the report acknowledged. Regulators are clearly cognisant of the need to move fast here – Moderna has already been allowed to test in volunteers with little preclinical proof of safety – and it seems that others will soon be following.

Leading coronavirus vaccine candidates		
Company	**Project**	**Detail**
Moderna	mRNA-1273	Currently being tested in healthy volunteers (US), NCT04283461
Cansino Biologics	Ad5-nCoV	Currently being tested in healthy volunteers (China)
Biontech/Pfizer	BNT162	Clinical trials due to start by end April
Inovio	INO-4800	US clinical trial to start in April, then China and South Korea
Others pursuing preclinical work include Sanofi, Johnson & Johnson and Curevac. Source: company statements.		