

# Information Request Email, September 16, 2014 - GARDASIL 9

**From:** Khurana, Bharat  
**To:** alison\_fisher@merck.com  
**Cc:** Montague, Laura  
**Subject:** STN 125508/0 (Gardasil 9); Information Request #18  
**Date:** Tuesday, September 16, 2014 3:36:00 PM

Dear Alison,

As we review STN 125508/0, we have the following Information request. Please submit your response as an amendment to STN 125508/0 by Sep. 30, 2014.

Subject AN 51204, a 13-year-old white girl from Spain in Study V503 -009, developed pulmonary vasculitis approximately two months after receiving the second dose of 9vHPV. Please provide the rationale for why this serious adverse event was considered not to be vaccination related. Additionally, please clarify whether antinuclear antibody (ANA) testing can be performed on pre-vaccination serum from this patient. If ANA testing was already performed, please provide the result. Additionally, please provide any available clinical laboratories, in particular complete blood count, from the subject's pre-vaccination medical record.

As always, please feel free to contact Laura Montague or myself if you have any questions. Thanks,  
Bharat

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