

**From:** [Kristi Raney](#)  
**To:** [Ventavia](#)  
**Cc:** [Olivia Ray](#)  
**Subject:** Pfizer Enrollment - PAUSE so we know we are ready!!  
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**Attachments:** [Outlook-pwvwwlxq.png](#)  
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Ventavia,

Olivia, myself and the leadership team made a decision this morning to pause our enrollment on the COVID C4591001 trial. Apparently, word travels fast in this company...and with that comes a lot of rumors. So let me help clear this up.

We have been enrolling fast and furious for 7-8 weeks now. Though we have participated in high-enrolling studies before, this one had it's own set of challenges from the beginning. Then to top it off...the enrollment period was extended for longer than we'd anticipated and that is HARD.

We realize that the more we enroll, the more chaotic and messy things get. We decided to pause our enrollment so that each of our COVID sites can not only catch up, but also make sure they are in complete compliance. I know I've said this several times, but I'll say it again here...it's not a matter of IF the FDA is coming...it's a matter of WHEN the FDA is coming. And they are coming soon. **This is the biggest clinical trial in the entire world...and we are a top enroller. THE FDA IS COMING....SOON** (like in a matter of days, if I had to make a guess).

I don't say all of this to scare you. I say this so that you can make sure you are prepared. And this is why we have decided to pause our enrollment. We need to do our own internal audit (as a team) and make sure we are prepared.

We will be having an FDA training in the next few days (in preparation), so be on the lookout for an invite...it will be mandatory. But until then, do not forget...if they knock on your sites door...the first thing you ask for **proof of who they are** (they will have the documentation you need to see) and immediately notify your manager and the manager will then notify the RD (and so on). SOMs...make sure anyone who answers our doors/sits at the front desks, know to immediately ask for identification if someone says they're from the FDA.

Let me know if you have any questions (don't cc all, unless necessary...I don't want the emails to get out of control with this)

**Kristi Raney**

Managing Member, Executive Director

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