

**From:** [Patel, Manisha](#)  
**To:** [Giordano, Erica](#)  
**Cc:** [Ahmed, Narin](#)  
**Subject:** BLA 125, 646 - Revised Form 3674  
**Date:** Tuesday, February 07, 2017 1:48:52 PM  
**Attachments:** [3674.pdf](#)

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Dear Erica,

Thank you for your call. Regarding Form 3674, it appears that the NCT for study A2205B was listed twice, and the NCT for study B2101J was left off (see table below). I have updated the form (attached), and will also submit it through the gateway. On the revised form, I have noted that it should accompany the submission in SN0000.

Of note, when we spoke on the phone you mentioned you saw 5 NCTs – please be aware that there are more listed on the 3<sup>rd</sup> page. There should be 10 in total. Let me know if you have any questions.

Study (sponsor)	NCT #
<b>Included on 3674 form in SN0000</b>	
B2202 (Novartis)	NCT02435849
C2201 (Novartis)	NCT02445248
B2205J (Novartis)	NCT02228096
A2205B (Novartis)	NCT02445222 <i>(listed twice by mistake)</i>
B2102J (Penn)	NCT01029366
A2201 (Penn)	NCT01747486
B2203J (Penn)	NCT02030847
A2101J (Penn)	NCT02030834
ZUS01T (Penn)	NCT02135406
<b>Missing on 3674 form in SN0000</b>	
B2101J (Ped ALL)	NCT01626495

Kind regards,  
Manisha

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