

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** Geriatric population  
**Date:** Thursday, February 19, 2015 11:38:19 AM

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Good morning –

Strictly from a FDA regulatory perspective, there are no restrictions. However you might want to consult a statistician or the sponsor of the study.

I hope this information is helpful. Please contact us again at [gcp.questions@fda.hhs.gov](mailto:gcp.questions@fda.hhs.gov) should you have additional questions.

Kind regards,

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This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

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**From:** [REDACTED]  
**Sent:** Tuesday, February 17, 2015 3:12 PM  
**To:** OC GCP Questions  
**Subject:** Geriatric population

Are there restrictions on collecting and / or publishing data on patients over 90 years in a clinical study where number of patients over 90 years is less than 3%.

Thank you for your support.