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COMPOSE

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**John Lamb** <john@lamb.uk.net>

to Alexander, derek

Sep 4 ★



Hi Alexander,
I have read Page 12 of your technical file section 9 " Clinical"

Was this a formal clinical trial as per Annex X or informal.

Do you have data on

The number of patients

Number of samples

Any side effects

Length of trial

Format of the protocol used.

On our last assessment it was pointed out to us that Formal Clinical trials are now required as part of the Technical File for Class 1 products.

This appears to be a grey area at present so please supply as much abbreviated information as you can and we will add it to our files.

Kind regards

**Alexander Yin** alexander99@yahoo.com [via](#) lamb.uk.net

to John

Sep 4 ★



Dear John