

Open Session I (WATKINS):

DR. SENIOR: We have our first speaker, Dr. Naga Chalasani, who is going to talk to you about: what is a transaminase?

DR. WATKINS: No, wait, I'm the moderator.

DR. SENIOR: Oh, right. Moderator Paul Watkins, taking over.

DR. WATKINS: All right. I do want to thank John obviously for putting together a terrific program, and I remember when he first started talking about it. He said we needed a much bigger venue, one that would include at least 200 people. I was the one that said, gee, do you really think that on this topic, which you discuss every year, that you really think 200 people would show up? Of course, his wisdom has always proved correct.

Can everybody hear like all the way in the back? Is there any problem with the sound?

Okay. So anyway, our first session is really focused on when an investigational drug should be stopped, particularly based on ALT elevations. As you know, the Guidance document says a number of things about ALT, including continuing use of the investigated drug until ALT rises up to eight times the upper limit of normal in a Phase III clinical trial. If the ALT is abnormal before starting, there's some mention of two times the baseline

serum ALT. These are the issues that I think we're going to want to explore in greater detail in discussion. As a way of background, we have three talks that really center on serum ALT levels. The first speaker is Naga Chalasani from Indiana University, and here's Naga.