DR. PEARS: Okay. Ladies and gentlemen, we hope your caffeine levels are restored. The excitement of criteria for inclusion/exclusion of people with underlying liver disease in clinical trials is done. Now you're ready to clear your head and discuss the next topic for the day. It’s related to the draft Guidance document we have before us, entitled Research Opportunities in the document. This really starts to address the issues about how we as a community that is interested in drug-induced liver injury are going to come up with better biomarkers, without really defining necessarily what better is.

We have three speakers here today who are going to give different views or different perspectives on the issues of biomarkers. As before, these are presentations really to stimulate discussion and debate. We will have a similar opportunity as we had in the previous session for panel discussion and grilling before lunch.

Just to set some context here, the aim of this session or the aim of the Guidance document isn't really to come to a situation where we will agree on some specific biomarkers. We're not going to agree even how to do assay validation or qualification of a biomarker in real life. That's not the purpose of this. It's more of a conceptual agreement about whether we believe that biomarkers for drug-induced liver injury will add any value prospectively

and how we potentially can work together or whether we will work separately, or whether we're going to do both, or is there another way of doing this so that we can actually become smarter about the way we assess the effects of drugs on the liver and the liver on drugs.