Questions to the committee

Question # 1

Please discuss the extent to which the phase 3 data provide persuasive evidence of diagnostic efficacy:

- **Consistency between the studies**
- **Comparator (SPECT) performance**
- **Added value to non-contrast ECHO**

Question # 2

Please discuss the extent to which the phase 3 data provide persuasive evidence of safety:

- Rate and nature of acute reactions necessitating AI-700 discontinuation
- Safety database size/single arm study design/stress as confounder
- Exploratory biomarkers of inflammation

Question # 3 (Vote)

Does contrast enhancement of rest/stress echocardiography with AI-700 provide sufficient diagnostic benefit to justify the risks associated with the product?

Question # 4

Please discuss the need, if any, for additional studies:

- **pre-marketing**
- **post-marketing**
- **nature of studies:**
  - **efficacy**
  - **safety**
  - **controls**