

**Questionnaire Page 2 - data collection sheet**

**Formal and content-related objections of coordinating ethics committees to first applications for clinical trials pursuant to § 7 (1 – 3) of the German Good Clinical Practice Regulation**

Company no. (serial)	Study no. (serial)	Ethics Committee	Objections per study (serial number)	Objection / Request (brief description of the issue, na = not applicable if no objection)	Evaluation Category	Study phase	Indication	Application submitted by sponsor/legal representative or Clinical Research Organization	Acted on objection (yes, no)	Comments