Irish Pharmaceutical Healthcare Association	**Data Protection Impact Assessments for Clinical Trials 06Dec24** **What are the responsibilities?**

1. The Sponsor, as data controller for clinical research purposes with the research data, commits to comply with all applicable data protection laws and regulations in the conduct of its clinical trials, such as those in Ireland. This includes performing a Data Protection Impact Assessment (**DPIA**) in accordance with Article 35 of the EU General Data Protection Regulation (**GDPR**).

2. It is not a responsibility for the Site to perform an additional DPIA as a data processor or to obtain, or verify, the DPIA performed by the Sponsor, and the Site should not do so. The Site may be under a separate duty to conduct its own DPIA to cover other processing activities where the Site acts as Data Controller, such as medical care, resulting in data processing in medical records. The Sponsor should not have any input into such activity.

3. In the case where the parties conclude that based on specific circumstances (such as collaboration on the development of the protocol) they are joint controllers, the parties will agree in good faith how they will perform the relevant DPIA.