1 We anticipate (and encourage) scientific collaborations with external partners. These will include requests for stored material and/or data relating to participants. Each request will be considered on a case-by-case basis.

2 Data sharing only: We adhere to the principles of the UK Concordat on Open Research Data, which recognises that research data should wherever possible be made openly available for use by others in a manner consistent with relevant legal, ethical, disciplinary and regulatory frameworks and norms, and with due regard to the cost involved.

The University of Liverpool owns the DolPHIN-1 trial data and samples. Both the data and samples are stored at the University of Liverpool. The DolPHIN-1 data sharing agreement outlines the types of permissible requests. Requests must meet the following criteria:

- No conflict with any existing DolPHIN-1 endpoints
- Has scientific and/or clinical merit
- Is ethically and legally acceptable
- Conforms to Data Protection requirements
- Does not pose any ongoing risk to trial participants
- Costs of supporting the research is covered
- Conforms with publication policy
- No issues around reputational risk or scientific integrity
- All Conflicts of Interest declared

Process: sharing will be underpinned by a Data Transfer agreement (or equivalent - eg as part of a research collaboration agreement or confidentiality disclosure agreement), with all originating DolPHIN-1 data remaining the property of the Sponsor. The integrity of the data in transit and storage will conform to GCP principles. The process of data cleaning and locking is necessarily careful and time consuming, and it is recognised that for certain studies, data can be transferred prior to data lock, providing that the recipient understands the risks of this, and the benefits outweigh the risks.

We will also identify a DolPHIN-1 investigator to lead the liaison for any external research collaboration.

3 For data and sample sharing the data-sharing principles in 3.2 will also apply, and in addition due consideration will be given to the integrity of the samples for the stated research purpose. As
custodians of all material collected, any request for samples must also be weighed against other (including future) projects which will compete for that sample, whether funded or unfunded. The DolPHIN-1 TMG will make a judgement for all potential requests, and any disputes may be referred to the Chair of the TSC.

4 We recognise that some collaborations involve pooling of data or samples, of which DolPHIN-1 only forms the minor part. In these circumstances we expect DolPHIN-1 contributions to still be recognised in any research output (including authorships) commensurate with the level of contribution. Where DolPHIN-1 forms the majority or totality of research material, the DolPHIN-1 Authorship and Publication Policy in section 2 above applies.

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