



## FAQ: Reimbursement Services

### 1. What needs to be considered when using external service providers for billing purposes?

Increasingly, external service providers are being engaged through which the trial participants can or should settle any costs. In this regard, the following aspects, among others, must be taken into account:

The involvement of a service provider must be addressed in the (main) informed consent form. If applicable, reference can be made to an external information document. If reference is made to an external document, this must be submitted as part of the CTIS application (see Annex I Sec. L No. 61 CTR).

The use of such a service provider should only be implemented as an optional service to the trial participant. Alternative reimbursement functions (e.g. via the trial site) should be offered that do not involve an external service provider.

It should also be ensured that the participant does not incur any cost risk (e.g. interest on arrears, costs in the event of loss of the debit card, fees for non-use, telephone numbers subject to charges, etc.). Information on dispute resolution must be available in German.

Only data necessary for payment transactions may be transmitted (principle of data minimisation). It goes without saying that care must be taken to ensure that the data protection information is complete and correct (including information on third country transfers where applicable). If the transfer to third countries cannot be avoided without an adequacy decision, standard contractual clauses must be concluded with the provider. If this is not possible, an alternative provider should be selected.

Note: The sponsor remains liable for costs.