May 2017

Sharing the costs of an individual study

Introduction

Seven co-registrants rely on the same study in their dossier. One of the seven co-registrants owns the study. The co-registrants need to agree on transparent, fair and non-discriminatory sharing of data and costs.

Determining the total cost

The cost of the study itself is just one element of the total cost. There are further related costs that the owner of the study details as follows:

Item	Justification	Cost (EUR)
Study cost	Price of the study, based on actual costs (invoice from laboratory, dated 2010).	160 000
Literature research	Before contracting the laboratory, a literature research was performed by a consultant to assess the available literature and to establish whether it would actually be necessary to perform the test (invoice from consultant, dated 2009).	20 000
Monitoring the progress of the study	The consultant was tasked to follow the study progress to ensure it would be suitable for the purpose of registration (invoices from consultant, dated 2010).	5 000
Financial management	The registrant had to request price quotations from different consultants to select the preferred one, and handle the invoices from the consultant and the laboratory (internal cost: estimate of required hours provided by data owner; hourly rate based on common practice and agreed by all co-registrants).	1 000
Scientific assessment of the study	The consultant assessed the study result and then prepared the IUCLID study summary for the lead dossier (invoices from consultant, dated 2010 and 2011).	14 000
Total cost		**200 000**

To show fair, transparent and non-discriminatory cost sharing, data owners have to justify the costs. This can be done in different ways.

In this scenario, for most items, the owner of the study can produce invoices to prove the actual costs incurred at the time the study was performed. For the internal costs where no invoices are available, the commonly agreed estimate of the hourly rate and time has been applied.

!	In general, when the study owner cannot show any invoice for the study costs, co-registrants could have agreed to use the cost of performing the same study according to the same quality standards again (replacement value). As the replacement value would be based on today's price quotes, while the actual study was performed several years ago, registrants may also agree to apply a discount which reflects the difference in price levels based on official data, e.g. from EUROSTAT.

Sharing the costs

Co-ownership

A possible way to determine the individual cost share per co-registrant is to agree on a co-ownership of the study. To achieve this, the total cost is divided by the number of co-registrants. Subsequently, each party has the same rights (ownership) related to the data. For the above scenario, this would mean:

	Cost (EUR)
Total cost	200 000
Number of registrants	7
Cost for each registrant	28 571.34

As one of the co-registrants was the original data owner, they would receive EUR 28 571.34 from the other six co-registrants. In total, they would get compensation for 6/7 (86 %) of the total cost.

Right to refer

Alternatively, the study owner can retain exclusive ownership over the study, and only grant the co-registrants the right to use the information for specific purposes, for example, their REACH registrations. Co-registrants need to make sure that the right to refer to the information covers all their needs related to their REACH registration, including preparing their safety data sheets and developing risk management measures.

In this case, the total cost is not divided equally between the co-registrants, but the total cost is broken into different cost factors, which indicate how much of the cost is borne by the study owner and how much is paid by the co-registrants.

Here, the co-registrants agreed to apply the following cost factors:

Cost factor	Justification	Factor	Calculation	Sum (EUR)
Total cost before application of cost factors				**200 000**
Right to refer only	The study owner retains full ownership over the data. This reduction reflects the fact that the other co-registrants get limited rights over the data compared with the study owner: they do not get full insight into the study nor co-ownership.	-50 %	200 000 * 0.5	-100 000
Discount for REACH-only use	The REACH market for the substance accounts for 70 % of the world market; 10 % of the market are for biocidal use within the EU, while 20 % are outside the EU.	-30 %	100 000 * 0.3	-30 000
Risk premium	The data owner took the risk that the test might fail. However, experience shows that this is a standard test, successful in 99 % of the cases.	+1 %	100 000 * 0.01	+1 000
Inflation	As some co-registrants are based in countries that experienced deflation in recent years, while others experienced inflation, the co-registrants mutually agreed not to take inflation into account.	0 %	0	0
Total cost after application of cost factors				**71 000**
Number of registrants	As in the above example, the total price is divided by the number of parties relying on the data for their REACH registration	7	71 000 / 7	
Total per co-registrant				10 143

As one of the co-registrants was the original data owner, this registrant would receive EUR 10 143 from the other six co-registrants. In total, the data owner would receive EUR 60 857, which is 86 % of the total cost *after* application of the cost factors, or 30 % of the total cost *before* application of the cost factors.

!	While co-registrants are free to agree on any calculation method, they need to make sure that each cost factor is objectively justifiable. This is crucial, as there might be further registrants, seeking access to the data in the future, who will need to be able to understand and agree with the chosen approach.