Financial valuation rules of existing studies

- The responsibility for the quality of data remains always with the registrant
- In case of joint submission: key studies need to be decided jointly (otherwise: opt out possibility if disagreement)
- The choice of the evaluation rules and the responsibility for this choice remain with the (individual) consortium

Rules for valuation of studies:

1. Reports are first evaluated versus **scientific value**, and only in second step the **financial value** is calculated via **mark-ups and deductions**
2. Aim: to ensure adequate compensation to report owner, and that recipient's requirement for a high quality report is satisfied

1. Scientific evaluation

- Reports = report + existing & available summaries (in the form of an IUCLID data set + robust summaries)

- Quality of reports = Klimisch et al. classification/ ranking ("1" reliable without/with restrictions "2", not reliable "3", not assignable "4") –see Klimisch publication, alternatively (technical) experts should develop Klimisch ranking for a report (also applicable for exposure studies)

2. Financial valuation

Proposal: only applicable for Klimish categories "1" and "2"; others = free of charge

Value: replacement value of the report as of the valuation date.

→ Current value = experimental costs + administrative expenses + risk premium

Included are expenses for setting up test:

- preliminary testing,
- substance testing (calculated via average from 3 european test institutes, for example)
- development of analytical methods,
- supplementary analysis (characterization, concentration, stability in test medium, etc),

- administrative expenses (professional support, travel, archival support, compilation of IUCLID data set, etc)

Deductions:

- in case of non-GLP, for example
- not exceed 20% of price for standard test

For surveys, for example:

- would need documentation of the process steps (including expenses and time required: development of concept, exploration studies, performance, analysis, expenses for further contractors, and administrative costs

Additional proposals:

- Robust summaries= compensated by 30 % of the value for administrative costs (see table below)
- Administrative costs can be evaluated on basis of experimental costs according to table below (via % surcharge)
- Risk compensation/premium → Fixed surcharge of 10% of experimental costs to be granted to contributing members (compared to new members)

Indication for administrative expenses:

Study value	**Administrative cost associated**	**% surcharge**
3000	**750**	**25 %**
5000	**1000**	**20%**
20000	**3000**	**15%**
50000	**5000**	**10%**
100000	**7000**	**7%**
200000	**10000**	**5%**
300000	**12600**	**4.20%**

For comprehensive cost sharing examples: see RIP 3.4 ECHA Guidance on Data Sharing (Annex 5)

Comments:

Whether using historic or replacement costs certainly additional correcting factors justifying an increase (eg radioactive test material, risk premium, etc) or a decrease (eg letter of access, robust study summary, regional restrictions, etc) of the value of a study, might be addressed.

For maximal efficiency, discussion and negotiation about study values should be focused only on the expensive studies. It may be economically advantageous, or from a time management perspective, wise, to negotiate costs of inexpensive studies. Compare maximum value costs of a study with costs spend for discussion (resource, time and efforts). Define general rules for less expensive studies. It may be appropriate to define costs for data packages instead of discussing all endpoints individually.

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