Introduction

Research projects conducted between academic researchers and industry sponsors require technical work plans, objectives, and reporting activities, and they also need accurate planning regarding financial and labor activity inputs. Budget planning is an essential element in preparing for negotiations, and, once agreed upon, a budget will standardly be incorporated into the final legal agreement, mostly in the form of an appendix or an addendum. This document deals with basic aspects of budgeting for collaborations and other forms of academic-industry projects.

To begin, it is useful to consider the objectives of the party with whom you are negotiating such a budget, and what sorts of activities and deliverables it may include that are related to their objective. An industry sponsor is likely to have a different set of objectives than its academic collaborator, and these are captured in the legal agreement that defines who gets what. The sharing of outcomes will determine the form of legal agreement that will be used as well as the budgeting format. Some types of arrangements include:

<table>
<thead>
<tr>
<th>Type of agreement</th>
<th>IP rights</th>
<th>Publication rights</th>
<th>Funding and budgeting approach</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research collaboration</td>
<td>May be shared</td>
<td>Publication generally acceptable with appropriate delay to evaluate patentability</td>
<td>Sponsor provides funding with budget rates reflecting equitable sharing of IP and publications</td>
</tr>
<tr>
<td>Fee-for-service or contract research</td>
<td>In most cases, sponsor would expect IP</td>
<td>Depends on sponsor’s intent, but results may be kept confidential and not published</td>
<td>Sponsor provides funding, with higher budgeted rates to compensate for inequitable IP and publication rights</td>
</tr>
<tr>
<td>Consortium funded by (public) grant with industry co-financing</td>
<td>In most cases, specific shared IP amongst consortium members</td>
<td>Pre-defined publication rights</td>
<td>Funded in large part by (public) grant or subsidy financing. Budgeting according to planned activities; often industry co-financing is relatively modest, relative to total project budget, and unrestricted</td>
</tr>
<tr>
<td>Investigator-initiated</td>
<td>Depends upon what partners contribute toward</td>
<td>Usually depends upon wishes of the party</td>
<td>May be fully or partly financed by external party;</td>
</tr>
<tr>
<td>clinical trial agreement with external party</td>
<td>the clinical trial; see a helpful overview provided by Duke Office of Clinical Research for more details on specifics of investigator-initiated trials; also see EU clinical trial site</td>
<td>providing the intervention, therapeutic, or IP being tested in the trial</td>
<td>please note, for the purpose of clinical trial agreements, that the term ‘sponsor’ has a specific legal definition.(^1)</td>
</tr>
</tbody>
</table>

\(^1\) According to REGULATION (EU) No 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC ‘Sponsor’ means an individual, company, institution or organization which takes responsibility for the initiation, for the management and for setting up the financing of the clinical trial
Mechanics of preparing a budget

A comprehensive budget will consist of the following cost categories, summed together and defined in terms of project phases when costs will be incurred – and when project outputs will be delivered - and a payment schedule reflecting when financial payment will occur. Each cost category specified in the following section much be considered and summed up in the final budget.

FTE

Full Time Equivalent employee - this is the number of employees and their specific roles that would contribute to the work plan. Each FTE of a given position would be based upon an annual allocation of their work hours, or FTE fraction thereof, which would allow the conversion of project labor requirements into budget salary and benefit requirements. For example, a project having 4 FTE, running for 2 years, would need to budget 8 FTE units of the appropriate annual salary and benefit amounts for the specific level of employees required in the projects. More information will be provided in the budget examples provided below.

Example hourly rates

Converting FTE to hourly rates is a simplified way to build a budget up from work plan activities:

1. Assume a project requires 0.5 FTE research technician for 1 year total;
2. Annual salary for the research technician position is €40,000 gross;
3. Assume benefits, insurance, and pension contributions comprise 45% on top of annual gross salary;
4. $1.45 \times €40,000 = €58,000$
5. Annual work hours for research technician FTE are 1,600 hours
6. €58,000 / 1,600 hours = €36.25 / hour
7. Because the position is 0.5 FTE, €36.25 * 800 hours = €29,000 budgeted for this position for the project duration of 1 year

Please note the following details:

- Standard salaries and benefit percentages may vary across European countries, although they are often standardized by national policy within countries;
- Annual work hours may vary from 1,500 – 1,800, but would standardly be calculated as hours available to work, and exclude holiday and vacation time;
- The above calculation assumes only cost coverage of the budgeted position, and accounts for no (profit) margin on top of the budgeted rate

Overhead

Overhead refers to indirect costs incurred by a party in the delivery of research activities, partly to cover costs on larger capital infrastructure that is broadly used and cannot be allocated to specific projects – ICT infrastructure, libraries, institutional electricity generation and so on - as well as to aspects of arranging and managing the projects that may be specific to the project.
The term ‘overhead’ can be confusing and should be carefully and transparently defined. For example, the above calculation of hourly rates includes an amount that covers indirect salary costs attached to the individual project FTEs, so these costs should not be added again. It would be more appropriate to add a percentage onto direct project costs, to cover indirect project costs incurred during project planning, contracting, and execution:

- Use of capital infrastructure;
- Coordination during project planning and contracting;
- Budgeting (both internal/departmental and sponsor-facing) as well as reconciliation;
- Legal support in agreement drafting, review, negotiation, and execution;
- Logistics and planning support for regular project communication;
- Project management, accounting and legal support;
- Supporting PIs in preparation of reporting documentation and final reporting;

### Access fees

If a project makes use of an essential asset which costs substantial time and money to construct or collect, and which was collected for another purpose – for example a database, longitudinal cohort, or collection of biosamples – an access fee may seem a fair and appropriate mechanism to compensate the party who collected it. In practice, the willingness of industry to pay access fees to academic parties may be low, and their negotiation position is likely to be quite strict. If in doubt, it may be better to request higher rates elsewhere, for example by rolling this up in the overhead percentage, to compensate for the use of this asset.

### Equipment time and depreciation

Research projects could make use of scientific equipment that is costly to purchase, operate, and maintain. If a project uses such equipment, the budget should attempt to estimate the hours for which it will be used, and derive a fair budgeted amount to compensate the party that pays for equipment purchase and upkeep. Equipment depreciation is typically based upon the useful life of the machine being depreciated – 5 years being somewhat of a standard period of use – and generating an annual amount which can further be calculated on an hourly basis.

Suppose a new machine costs €300,000, has a 5-year lifespan, has a trade-in value of €50,000 at the end of 5 years, and is used for 500 hours per year:

- €300,000 (purchase cost) - €50,000 (trade-in value) = €250,000
- €250,000 / 5 years = €50,000 per year
- €50,000 /year * 1 year / 500 hours = €100 / hour

This machine can therefore be budgeted at €100 / hour for direct use within the project, multiplied by the number of hours the machine will be used.
Reporting, milestones, deliverables, go/no-go, and payment schedule

These terms are interrelated aspects of project management and financial control, and relate to how the project is measured and financial compensation for project activities is delivered. Here are the details:

1. Projects are typically broken up in phases in which the project progress is reported and can be evaluated against the work plan.
2. At the end of each phase, projects are expected to generate ‘milestones’ or ‘deliverables’ as project outputs.
3. Project phases may end in a ‘go/no-go’ decision in which the sponsor may evaluate project performance in terms of the investment it has made.

Conveniently, the timing of this reporting should correspond with the financial obligations of the sponsor to pay out the agreed-upon amounts of funding.

Let’s use the following example for a project that is expected to last 1 year and that has a total value of €100,000:

<table>
<thead>
<tr>
<th>Milestone Deliverable</th>
<th>Estimated date</th>
<th>% of total budget / Payment amount</th>
<th>Payment due date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study start up, ethical approvals obtained and study site open to recruitment</td>
<td>End of Quarter 1</td>
<td>25% / €25,000</td>
<td>x days to send the invoices and y days for them to be paid, where x and y will depend upon local tax and other regulations and policies of the institute (being typically in the range 14 to 60 days)</td>
</tr>
<tr>
<td>Study opening and first patient recruitment</td>
<td>End of Quarter 2</td>
<td>25% / €25,000</td>
<td>Payment by Sponsor within sixty (60) days of the date of receipt of invoice.</td>
</tr>
<tr>
<td>Go/No-Go decision, estimated midpoint of study</td>
<td></td>
<td></td>
<td>If at least 50% of samples are not collected, the project will be terminated with remaining payment schedule to be reflected in agreement termination clause.</td>
</tr>
<tr>
<td>Delivery of all samples (approximately 80 samples) to Sponsor</td>
<td>End of Quarter 3</td>
<td>25% / €25,000</td>
<td>Payment by Sponsor within x days of the date of receipt of invoice.</td>
</tr>
<tr>
<td>Completed end-of-study review by Principal Investigators</td>
<td>End of Year</td>
<td>25% / €25,000</td>
<td>Payment by Sponsor within x days of the date of receipt of invoice.</td>
</tr>
</tbody>
</table>

Please note the use of deliverables that include essential project management and administration activities (‘ethical approvals obtained’) as well as direct project activities (‘first...
patient recruitment’, ‘delivery of all samples’). Activities such as ethical approvals can be both time consuming and lengthy in duration due to internal administrative processes in academic settings. Both activities are essential for the initiation and conduct of the project, and are appropriate to use for determining sponsor payment schedules.

The use of a go/no-go decision point in this project ensures that the project delivers according to schedule. In common practice, such decision points permit some flexibility due to unforeseen complications.

**Cost basis, profit, and tax implications**

It is never advisable to conduct research projects at a budget below what is known to be the fully-overheaded internal cost price. This is both unfavorable for the reputation and financial health of the research provider, as well as potentially being illegal under EC rules in that the provision of such services can disrupt functioning markets. Therefore, it is essential the budget reflects the actual, known costs of providing such research project capacity to the best extent known.

The addition of budget items to provide profit margin may – or may not - be permitted under institution and country rules.

If any budgeting question should arise, it is best to seek institutional advice from a technology transfer or external research office. They can also help to provide tax guidelines in regards to national tax regimes, which can vary widely amongst countries.