

## Chapter XVII

### BUDGET AND FUNDRAISING

Pierre Duhaut, Jean Schmidt, Claire Andrejak, Jean-Pierre Ducroix

Budgeting is an important part of developing a research project:

- On the merits, it must take into account all the elements of the project involving a cost, both of operation and of equipment (material). It includes salary costs (employment of technician or research assistant). It reflects the feasibility of the project.
- On the form, he must respect the indications provided by each fund-raiser call: non-respect will often lead to the rejection of the project without the substance being examined.

There are many fund-raiser calls every year. This chapter proposes to review them by broad categories, but it will also be appropriate, for a given project or subject, to carry out a systematic search of the possible sources of financing, currently exposed on the Internet.

Clinical research for a very long time did without individualized funding, because its costs were borne globally by the institutions in which it was carried out (hospitals and universities). These costs, however, have always been real and are divided, as always, between operation and equipment. Credit applications must explicitly detail these two major items in the budget, and precisely cover the specific points for each research project to specify the amounts in a credible manner.

#### I- THE BUDGET

The plan is specific to each request, and it is advisable to check before submitting the request the conditions laid down by the call for tenders: some calls for tender only concern the operation, others (rarer), the equipment.

##### A- Operation:

It includes salaries (including charges), and all direct or indirect expenses related to the collection, analysis, and presentation of data from the research project.

**1- Wages:** It is currently difficult to design a clinical research project without a clinical research technician (or assistant) whose role will be to ensure practical coordination between the various centers for multicentre projects (opening of centers on site, installation computer tools), data entry, management of missing data (important part of the work), regular sending of follow-up questionnaires, etc. The skills required may be those of a secretary mastering computer tools or a technician (BTS or more) mastering the laboratory, imaging, or computer techniques necessary for the project. The budget must mention the number of full-time equivalents and the salary, charges included (employee and employer) per year and for the total duration of the project. The amount of salaries and charges is usually based on the salary scale of the institution in which the person hired will work. Salaries are usually the largest

part of the requested budget. In the case of fixed-term employment, it will also be necessary to provide for severance pay based on the foreseeable duration of employment.

**2- Small equipment:** it is part of the operating costs, and includes all computer maintenance equipment, office supplies, small laboratory equipment (pipettes, etc.), reagents if necessary.

3- Costs relating to **communication** between centers: mail, telephone, fax, etc.

4- **The additional costs** induced by the project on the patients to be included: they include in particular the cost of all the additional examinations not justified by the actual medical care of the patients included. They can be important in the case of imaging (MRI, PET-scan) or biological assays (radio-immuno-assays, etc.). Each act, however, is affected by different costs: the cost price is very often very much lower than that indicated by the Social Security nomenclature (B, Z, etc.), and these prices can be negotiated with the institutions involved in the process. project (biology laboratories, imaging services, etc.).

**5- Costs of storing** biological samples (Biobank).

6- The costs relating to the necessary **transport** between the various participating centers, possible accommodation: in public and private companies, there are standards according to the distance traveled and the type of transport.

7- The costs relating to **data entry** if it is subcontracted to a specialized company.

8- Costs related to **data analysis** if it is not done by one of the project investigators.

9- Costs relating to the **communication of results**, particularly in congresses or in journals with a high impact factor, some of which impose a rate per page or even per illustration.

10- **Overheads** levied by certain institutions (premises, geaccount station)...

11- The costs of going to the personal **protection committee** (former ethics committees)...

12- Any other **identifiable cost**...

## **B- Equipment:**

It must often be the subject of a separate procedure, in different calls for tenders. The equipment costs are, for example, the purchase of computer equipment dedicated to the planned study (microcomputer, physical backup means, data protection means, etc.), a measurement tool essential to the study (equipment laboratory, excluding consumables which are included in operating costs)...

*It is important for the credibility of the application that each budget line refers to a specific stage of the research project, and that each stage requiring funding is represented in the budget. A project may be the subject of several funding requests: it will then be necessary to specify what part of the budget is requested from each source of funding.*

A budget that does not respect the form of the call for tenders to which it responds will have every chance of being rejected without being examined on the merits.

## **II- SOURCES OF FUNDING**

They are multiple and may vary from year to year. We will consider some of the most constant at the present time, knowing that multiple factors foreseen (elections...) or unforeseen (crises...) can modify the amounts and that a source of financing can only rarely (never ?) be considered sustainable. The information currently passes through the Internet, and the sites of the various organizations should be consulted on a regular basis. Information through institutional channels is much slower and sometimes arrives after... the deadlines for submission have expired.

### **A- Major sources of public funding:**

They have the immense advantage of guaranteeing a certain freedom of research at the present time. They correspond to specific themes, defined by period (years, or duration of a plan), by the corresponding public authorities.

#### **1- The Ministry of Health:**

##### **- At the national level:**

The clinical research hospital program (national PHRC). It has existed in France since 1993 and has been launched almost every year since. It covers 5 to 6 major specific themes defined each year (rare diseases, Alzheimer's, evaluation of new technologies, etc.) and follows a precise timetable for submitting the project idea (usually at the beginning of the calendar year), then of the full project (usually in the first quarter of each year). It is backed up by a special 'Cancer' program with similar terms. It promotes multicentric and multidisciplinary projects, and can provide funding ranging from one to several hundred thousand Euros per project for a period of 3 years.

##### **- At the inter-regional or regional level:**

A second hospital clinical research program is coordinated at the regional or inter-regional level, and promotes research projects stimulating cooperation between hospitals in a region or inter-region. The call for tenders is currently launched each year, it precedes the call for tenders of the national PHRC, and allows funding of around one hundred thousand Euros for a maximum period of 3 years. The same project cannot be submitted at the national level and at the regional or inter-regional level simultaneously.

##### **- At the local level:**

\* Hospitals also have budgets under a local PHRC, which can usually finance projects of the order of ten or several tens of thousands of euros. The calendar and potential themes are set by each hospital. ii.

\* System for Querying, Management and Analysis of Scientific Publications (SIGAPS): since 2007, all university hospitals, at the request of the Ministry of Health, have been equipped with this software making it possible to identify the publication activity of a service. Basically, the software takes the publications reported in PubMed (Medline) on the basis of the name of the authors and then re-assigns them to the services and the poles. The share of the CHU's annual budget theoretically devoted to research is calculated on the basis of the SIGAPS index, and can reach 13% of the overall budget.

These very large budgets are accounted for in France's research effort... but it is up to the CME (Commission Médicale d'Établissement) and each head of department or division to negotiate with the management of the hospital effective allocation, at least partially, to research-specific activities. It is recalled that the time spent on research by university hospital staff cannot be deducted from this budget and that it must be considered as part of university half-time.

## **2- Major public research organizations:**

They are currently grouped under the aegis of the National Research Agency (ANR), which centralizes calls for tenders and awards previously divided between INSERM, CNRS and other organizations. The website (<http://www.agence-nationale-recherche.fr/Accueil>) should be consulted regularly.

## **3- Regions, departments and local authorities:**

### **- Regional Public Health Groups (GRSP):**

These groups are chaired by the Prefect. They are made up of the State [State services: DRTEFP (Regional Directorate for Labour, Employment and Vocational Training), DRPJJ (Regional Directorate for Judicial Protection of Youth), Rectorate], its public establishments [INPES (National Institute for Health Prevention and Education) and INVS (National Institute for Health Monitoring)], ARS (Regional Health Agency) which has replaced the Regional Hospitalization Agency since 2009, Health Insurance [URCAM (Regional Union of Health Insurance Funds) and CRAM (Regional Health Insurance Fund)] and volunteer local authorities. Tenders are usually published twice a year and primarily concern public health issues (in the broad sense of the term). Associations can be funded provided they have a SIRET number (essential to be able to benefit from public funding). The websites to consult are specific for each region.

### **- The Regional Councils:**

They have significant financial resources managed specifically according to the regions. In most regions, there is a budget ear-marked for research. Depending on the region, funding can be obtained through calls for tenders issued either directly by the council or through regional institutions such as university hospitals or universities.

### **- The departments, the cities:**

may also support research actions, and these possibilities are to be explored on a case-by-case basis.

## **4- European funding:**

A significant part of the European Union budget is devoted to development and research. If the industry (aeronautics in particular) takes the lion's share, health and life sciences are not neglected. France is less present in the allocation of budgets than the Nordic or English-speaking countries, and has undoubtedly neglected this source of funding for too long.

The priorities are defined after an international consultation in five-year programs, called 'Programmes-Cadres' (PC) or 'Framework Programs' (FP). FP7 began in 2007 and will be extended over a period of 7 (and no longer 5) years. Calls for tenders in different fields are launched each year, the terms of which can be consulted on the CORDIS site

([http://cordis.europa.eu/home\\_fr.html](http://cordis.europa.eu/home_fr.html)). Funding concerns multinational projects most often involving at least three countries of the European Union and/or allied countries (Switzerland, Israel), often multidisciplinary. The files must imperatively correspond to the fixed themes. A year of file preparation is to be expected if we want to meet the requirements of the program, and the calendar of calls for tenders should therefore be consulted regularly. Specific programs (rare diseases, specific pathologies) may be the subject of independent calls for tenders with specific terms and conditions, but can be listed on the CORDIS site.

Specific budgets are also provided for the exchange of researchers ('Marie Curie' Actions).

To facilitate the constitution of files, specific 'National Contact Points' for the different fields of research have been set up in the different countries. Their contact details (e-mail address and geographical location) are specified on the CORDIS website. The national contact more specifically in charge of clinical research in France is usually part of the Research Delegation of the 'Assistance Publique des Hôpitaux de Paris', and it is strongly advised to consult it before embarking on the procedure.

## **B- Sources of private or public/private funding:**

A large number of sources cover an extremely wide field of pathology and possible related research. The budgets allocated by these sources are generally more modest than those offered by major public tenders. However, they are not to be neglected, because a project may have a better chance of being financed when it benefits from multiple supports. In addition, these sources can finance specific aspects, and very often young researchers or their mobility.

### **1- Learned societies:**

Their site must be systematically consulted, in particular for funding for residents/interns and assistants embarking on a research project, or seeking funding for a year of master's or mobility, in particular within the framework of a science thesis: various scholarships can be offered, which can be combined with others in order to cover all the costs incurred.

### **2- The foundations:**

Multiple foundations, most often related to a specific pathology, a group of pathologies (neurodegenerative conditions, etc.) or a particular symptom (visual disorders, motor disability) can finance clinical research projects aimed either at direct improvement of patients' living conditions, or deepening of fundamental knowledge. Some of these associations-foundations are very famous and widespread throughout the territory (National League against Cancer, Association for Research against Cancer, Téléthon, Sidaction, etc.) and can finance projects of all kinds at regional or national level. Most are less well known and deserve to be systematically researched on the web according to the subject of research. Certain calls for tenders may also be published on the website of the National Research Agency (ANR).

The Academy of Medicine in this regard operates as a foundation and annually awards prizes of a very variable amount, from legacies for which the donor has issued a particular orientation. Young doctors, in particular, can benefit from scholarships or funding within the framework of masters or theses.

### **3- Industry and businesses:**

The financing offered corresponds to the interests of companies and is therefore particularly oriented (example: nutrition for diabetics, children, infants, etc.). The particular case of the pharmaceutical industry is to be considered: more and more, it builds, coordinates, analyzes, and publishes its own projects, and the doctors 'investigators' in fact... include patients without any other participation in research (from the way to ask the question until the writing of the articles!). The question of the independence of the research, of the objectivity of the analysis, of the interpretation and publication of the results must therefore be raised, and, insofar as the funders of this corporate research are ultimately the health insurance systems, a more balanced partnership between producers of treatments and clinical research must be invented in order to regain the freedom of university or hospital research, to avoid the mixing of genres (fundamental research and production/evaluation and clinical application/training of young doctors and continuing medical education/marketing decision/recommendations or even enforceable recommendations), and work better for the well-being of patients...

## **III- FUNDING STRATEGIES:**

In general, the constitution of a good file is long. Several rules must therefore be observed:

### **1- The calendar of calls for tenders:**

It must be anticipated by referring to the dates of the previous year. These dates can sometimes change, but the time between the launch of the call for tenders and its closing is most often too short for the drafting of a first request from a clinician inexperienced in this type of file, and often overwhelmed by his clinical activity. The correct construction of a first project (master type for example) can take 6 to 9 months, even if history abounds in poorly constructed and well financed projects. Experience shows that shortening this time too often leads to projects that may look good, that eventually can be financed, but that will come up against many difficulties of practical realization or analysis, considerably limiting the value. An architect does not build a tower on a draft or approximations... and the living is more complex than the inert. The possibility of funding a clinical research project must be taken into account from the start (this is the question "is my research idea feasible"). However, you should not confuse filling out a funding application file with writing the protocol for your study. First of all, your protocol must be well constructed and thought out, before hoping for funding.

### **2- The themes of the calls for tenders:**

They must be respected... just like the form imposed by the funding body: this aspect may seem secondary but can be a key element in the decision. A file that is incomplete or does not correspond to the presentation requested is often rejected without even having been assessed on the merits.

### **3- The size of the project:**

National, regional or local structures most often finance projects on their scale: it is therefore necessary to choose the call for tenders corresponding to the dimension of the

project, both in terms of the budget (a study on a frequent pathology can be carried out on only a few sites, but be of a sample size requiring national PHRC-type funding), in terms of patient recruitment sites and inter-disciplinary collaboration (ranging from local to international).

#### **4- The age and qualifications of the principal investigator:**

A resident, even a doctoral student, cannot, in the current state of things, be the principal investigator of a project submitted to the national or inter-regional PHRC. The project must therefore be led by a senior even if it was designed by a younger colleague. Conversely, a certain number of scholarships and prizes include an age limit, which is quickly reached in the medical profession: it is therefore necessary to encourage residents and young assistants to apply for them, and to supervise their work which can also be integrated into a larger service or unit project. This is all the more necessary since obtaining larger budgets of the PHRC type is partly conditioned by the previous publications of the principal investigator and the associated investigators: *there as elsewhere, it is easier to lend to the rich...* and it is necessary to therefore worry about establishing the wealth of those who will be able to apply in the next few years, under penalty of a rapid collapse of the research activity of a unit. The Research and Innovation Departments of the University Hospitals can also help you in several stages. These structures are informed of calls for tenders and their schedule. They can provide “advice” in the establishment of your funding application files, the requirements and formatting of which are sometimes confusing at first sight.

#### **5- Number of projects per service or unit:**

A single clinician cannot, for obvious reasons of availability and competence, carry out several research projects at the same time: the same project must make it possible to deepen different aspects if one wants to remain at the forefront in his field. On the other hand, it can be risky for a service to invest only on a single theme: many resources (research technician, logistical resources, IT) can be pooled on a few different clinical research projects and will therefore have more chances of being continued if a theme goes out of fashion or if by chance a well-started project runs out of funding. *Here as elsewhere, mutual aid that is well understood can benefit everyone.*

The Clinical Investigation Centers can meet this objective by providing a structure (premises, computer resources) and personnel (clinical research associates), at the condition your specific project is funded.

#### **6- Funding failures:**

They are an integral part of any background research, and can be motivated by more or less objective reasons. They can be used to improve a submitted project when the criticisms of the experts are constructive; but all human activity is subject to human vagaries, and failures should never be used as a pretext for giving up when the critics are not up to the idea or project submitted... the history of science and medicine is full of ideas rejected and passed on to posterity! In a more modest way, a valid project must often be submitted to several calls in order to be financed, and it must undoubtedly be started at least partially from the first financing obtained to have a chance of being able to complete it later.

**Important points :**

- Anticipate calls for tenders, to take the time to build them correctly while respecting the terms and form.
- Include in the budget all elements, but only those elements, of the project precisely described in the procedures.
- Regularly visit the sites of funding sources.
- Encourage the youngest to submit their projects to the appropriate structures, to allow them later access to more important calls.

**But also :**

- Have more than one project in the same team, with one coordinator per project

**And even :**

- Independence – of design, analysis, publication – is undoubtedly one of the ingredients of quality in applied clinical research.
- All required qualities being equal, a little stubbornness is necessary for the construction and realization of a project.