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Carole Haritchabalet, Catherine Bobtcheff

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EXPERTISE IN THE RELATIONSHIP BETWEEN BIOBANKS AND RESEARCH UNITS

Catherine BOBTCHEFF

Carole HARITCHABALET

CATT-UPPA
UFR Droit, Economie et Gestion
Avenue du Doyen Poplawski - BP 1633
64016 PAU Cedex
Tél. (33) 5 59 40 80 61/62
Internet : **http://catt.univ-pau.fr/live/**

Expertise in the relationship between biobanks and research units

Catherine Bobtcheff, Toulouse School of Economics & Toulouse Capitole University (CNRS)

Carole Haritchabalet, University of Pau and Pays de l'Adour, CATT & Toulouse School of Economics

0. Introduction

We propose to model the relationship between a biobank and a research unit. We are interested in the problem of a research unit that wishes to invest in a new project. This project can potentially lead to a new drug or process whose profitability is uncertain. This project requires access to a collection of biological resources (biological samples and associated data) stored in a biobank. The commercial value of this innovation is unknown by the biobank and the research unit, but it is endogenous, i.e. it depends on the actions and decisions of the different actors. Our objective is to identify how these actions and decisions modify the value of the innovation.

We choose to place the expertise of the biobank at the center of the relationship between the actors. We believe that the role of the biobank is fundamental in the process of project selection (and therefore in the decision to allocate samples), but also to improve the chances of success of the project. Our central hypothesis links the biobank's level of expertise to its ability to evaluate the project and to contribute to the success of the innovation. An experienced biobank will be more selective than a less experienced one but will be better at providing good-quality samples, thus improving the likelihood of success of the innovation.

Expertise is not the only important element in the success of innovation. The members of the biobank can become engaged in the success of the project. This possibility of getting involved in the project's success creates amoral hazard problem.[1] A contract between the biobank and the research unit cannot be established on unverifiable variables. While certain actions of the biobank can be easily evaluated, there remains a certain amount of leeway for the biobank in its levels of commitment. This level of commitment or 'effort', which no jurisdiction would be able to verify, is the source of the moral hazard problem.

We analyze the interaction between level of expertise and conditions of the exchange (terms of the contract) on the decision about the biobank's effort. We identify the economic inefficiencies of this relationship and propose recommendations in terms of public policy. This analysis sheds light on the issues related to biobank specialization.

I. Modeling

A research project's success and its value to society[2] are uncertain. They depend on exogenous factors (such as the general economic situation, demand for the molecule on which the research is focused, current legislation, project costs, etc) and endogenous factors such as the biobank's level of expertise, the number of samples in the project, and the biobank's level of effort.

We assume that the interactions between the biobank, the research unit and the value of the research project have the following sequences and characteristics.

[1] Moral hazard refers to a situation where the behavior of one party may change to the detriment of another after a transaction has taken place.

[2] The social value of the project includes all the returns of innovation (monetary and academic returns, improvement of knowledge…).

I.A The research unit

We consider a research unit that wishes to engage in an innovative project. The research unit is ready to invest a fixed amount I in this project. The development of this innovation requires biological samples stored in a biobank. This project cannot be undertaken if the biobank refuses to make the samples available.

In our model, the role of the research unit is limited. We consider that the amount invested is fixed. Once it has decided to launch the research project, we assume that the research unit must choose the number of samples needed for the project. The problem of choosing the expertise level of the biobank is discussed at the end of the document. The public or private nature of the research unit is not specified.

I.B The biobank

We consider a biobank with a given level of expertise or experience (denoted by α) with the required samples to participate in the project. This level of expertise is known to the research unit and is linked to the biobank's strategic positioning choices (specialization, quality). The operation of this biobank involves fixed and variable costs. These costs may depend on the expertise level.

In our model, we consider that the biobank must take two decisions. Firstly, the biobank must decide to accept the project or not. If the project is accepted, the biobank must secondly decide whether or not to get involved in the success of the project. Our analysis is initially centered on the biobank's level of expertise. The decision to specialize is discussed later.

We assume that the level of experience of the biobank is fundamental to evaluating the project. A highly experienced biobank is more effective in its selection process. Expertise makes it easier to distinguish good and bad projects. Only a project offering a positive expected return to the biobank can be accepted. Once a project has been accepted, the biobank determines its level of involvement in the project. Involvement can be understood here as any possible investment of the biobank in the project (additional work on the samples or scientific collaboration between the biobank and the research unit). We call effort any form of involvement of the biobank which is not verifiable and thus cannot be included in the contract. This effort improves the success of innovation. We assume that the biobank can choose to exert the effort or not. There is thus a problem of moral hazard in the relationship. The biobank will exert an effort if, and only if, the benefits of the effort allow it to cover its costs.

I.C A project's social value

Our main assumptions regarding the relationship between these endogenous variables and the value of the project are as follows:

- H1: A more experienced biobank is, *ex ante,* better at detecting good projects.
- H2: Once a project has been accepted, the more experienced the biobank, the higher the probability of successful innovation.
- H3: The greater the biobank's effort, the higher the probability of successful innovation. As the effort is costly, systematic effort is not necessarily desirable. We assume that effort becomes relevant only above a certain level of experience.

- H4: There is a socially optimal number of samples, i.e. a precise number of samples that maximizes the social value of the project.

The social value of the project, denoted by V, takes into account all the benefits (expected revenues from innovation) and costs associated with the implementation of the project (investment by the research unit, fixed operating cost of the biobank, cost of sample production, cost of effort).

It is socially optimal to undertake the project if its social value is positive. We talk about insufficient innovation when good projects are not undertaken and about excessive innovation when bad projects are undertaken. It is socially optimal for the biobank to be involved in the project if it increases the social value of the project.

I.D Sharing innovation

The social value of the innovation V is shared between the biobank and the research unit. The value of the project for each agent (its profitability) is the sum of its private costs and benefits associated with its participation. The uncertain nature of innovation implies that there is income from innovation only when innovation is successful.[3] If V_b and V_r denote the expected private values of the biobank and the research unit, then $V=V_b+V_r$.

This value is shared by a contract specifying the various payments from the research unit to the biobank. We choose a contract composed of a fixed transfer F, a tariff for each sample exchanged t and a royalty rate r which determines the share of income from the innovation left to the biobank. The effort decision of the biobank is not verifiable and cannot be included in the contract.

Whatever the outcome of this innovation, the biobank receives the revenue associated with the exchange of samples and the fixed transfer. The biobank bears different costs: a fixed cost, a variable cost of production and potentially a cost of effort. In addition to the cost of investment in the project, the research unit must compensate the biobank for each sample and offer the fixed transfer.

A project is accepted by both partners (and thus proposed by the research unit to the biobank) if, and only if, the contract allows them to obtain a positive expected value: V_b and V_r must therefore be positive to ensure the participation of the two agents in the project. This implies that the expected social value of the project is also positive ($V=V_b+V_r$). Only socially desirable projects can thus be undertaken. The relationship between the biobank and the research unit does not lead to excessive innovation, but may lead to a problem of insufficient innovation (some projects with a positive social value may not be undertaken).

If the biobank accepts the project, it will be involved if, and only if, its profitability when it exerts effort is greater than its profitability when it is not involved in the project. It will be necessary to study the existence of problems of under-provision or over-provision of effort.

II. Results

We now determine the impact of the relationship between the biobank's expertise, the effort decision and the different terms of the contract on the social value of innovation. We

[3] The revenue of innovation R is strictly positive if innovation succeeds, it is zero if innovation fails.

take the perspective of a regulator wishing to maximize the social value of the project: the decisions of the actors must create the greatest possible value for society. To achieve this objective requires choosing how to determine the elements of the contract. We address in turn the important elements of this relationship.

II.A What tariff for samples?

The first question is the choice of the tariff *t* for which the agents will exchange the samples. This tariff is a tool for transferring income from the research unit to the biobank and compensating the costs of producing the samples. It also determines the number of samples exchanged between the research unit and the biobank.

We know that there is an optimal number of samples that maximizes the social value of the project (hypothesis H4). This number is such that the expected marginal value of a sample (the marginal value of a sample for successful innovation) is equal to its marginal cost.

If the decision on the number of samples is left to the research unit, it chooses a number of samples such that its marginal cost, the tariff *t*, is equal to its marginal benefit. The marginal benefit of a sample is the share of the expected marginal value of the sample that is received by the research unit. This share is determined by the royalty rate: the research unit receives a share *(1-r)* of the revenues from innovation. The marginal benefits and costs of a sample for the research unit are then different from their social marginal benefits and costs. There is therefore no reason for the number of samples requested by the research unit to coincide with the socially optimal number. The sample price and the royalty rate are thus factors that can reduce the effectiveness of the innovation through the choice of an unsuitable number of samples. We can establish that the demand for samples from the research unit decreases with the royalty rate *r* and the price *t*.

For the biobank, the marginal cost of a sample is the marginal cost of production. Producing a sample allows the biobank to obtain a compensation *t* and a share *r* of the expected marginal value of the sample. The choice of the number of samples offered by the biobank depends on the difference between the marginal cost of production and the tariff *t*:

- this number *increases* with the royalty rate *r* when its tariff is higher than its marginal cost of production;

- this number *decreases* with the royalty rate *r* when the tariff is *lower* than its marginal cost of production.

The sharing of the expected marginal benefit of a sample between the two actors leads the agents to select an unsuitable number of samples (relative to the social optimum). For example, when the tariff is zero, all the variable costs of sample production are borne by the biobank: the research unit selects too many samples whereas the biobank does not choose enough. When the price exceeds the marginal cost, the marginal benefit of a sample increases for the biobank that produces an excessive number of samples.

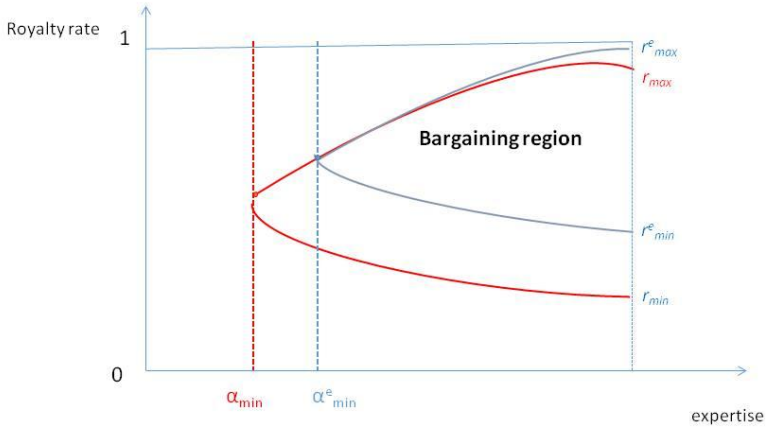
It is possible, however, to determine a sample price such that each actor prefers the socially optimal number of samples. The marginal costs of production *c* must be shared along with the income from the innovation: the pricing rule $t=c(1-r)<c$ allows socially optimal sample production to be achieved. It is therefore optimal for biobanks to bear part of the costs

of producing the samples and to provide the samples at a lower price than the cost of production.

II.B Participation, Contracts and Expertise

A contract *(t,r,F)* must guarantee each agent a positive profitability so that they agree to participate in the project. Let us suppose that the tariff of the samples complies with the rule stated above and assume a fixed transfer *F*. Suppose also that the effort of the biobank can be observed (and therefore included in the contract).

The constraints of participation of each actor restrict the possible values of the royalty rate to an interval denoted as $[r_{min}, r_{max}]$ if the biobank does not exert effort (or $[r^e_{min}, r^e_{max}]$ if the biobank carries out an observable effort).[4] These intervals are interpreted as follows. All royalty rates in the interval are possible solutions in the negotiations between the biobank and the research unit. A royalty rate outside the interval does not allow the implementation of the project because at least one of the agents prefers not to participate. The lower bound of the interval represents the minimum royalty rate that must be left to the biobank for it to agree to participate in the project. The upper bound of the interval is the maximum royalty rate that the research unit will agree to leave to the biobank. These royalty rates are defined for each possible value of the expertise level of the biobank. We can thus construct curves representing the evolution of these rates as a function of the level of expertise. The value of the project for the biobank is zero along the curve r_{min} (or r^e_{min} if it exerts effort). It is strictly positive for any strictly higher royalty rate. The value of the project for the research unit is zero along the curve r_{max} (or r^e_{max} if it exerts effort). It is strictly positive for any strictly lower royalty rate.



The issue here is not to determine the royalty rate arising from negotiation. The outcome of the negotiation between the biobank and the research unit is determined by the alternatives available to the agents when the negotiation fails. It is the degree of competition between biobanks that is fundamental to understanding the outcome of such a negotiation.

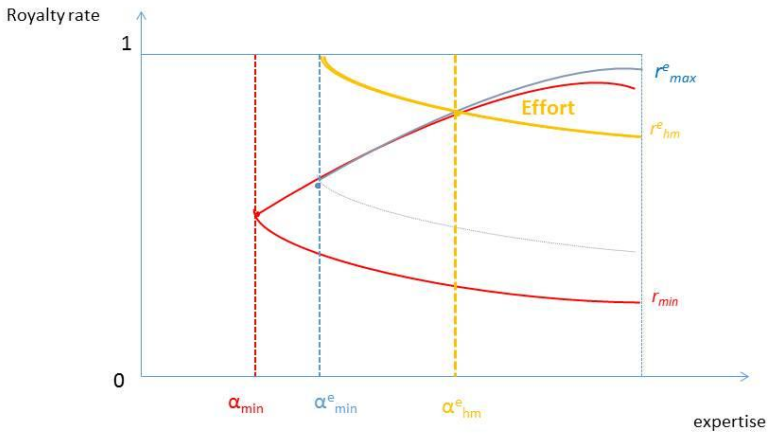
[4] These intervals are included in [0,1].

Formal analysis allows us to understand the conditions that favor this negotiation, looking at how this interval is shaped by the characteristics and decisions of the biobank. First, it should be noted that the interval exists only if the biobank is sufficiently experienced (experience greater than α_{min} or α^{e}_{min}); and this interval widens with the biobank's level of expertise. This result stems from the positive relationship between the probability of innovation success and biobank expertise (hypothesis H2). Next, this interval depends on the effort decision of the biobank. Thus, an inexperienced biobank can become involved in a project but it will not exert effort ($\alpha_{min} < \alpha^{e}_{min}$). Indeed, because effort is costly, a larger share must be left to the biobank: the minimum royalty rate increases from r_{min} to r^{e}_{min}. The research unit, on the other hand, does not bear the cost of the effort but reaps its benefits: the maximum royalty rate that the research unit agrees to leave to the biobank increases with the effort r_{max} to r^{e}_{max}. It should be noted that the values α_{min} and α^{e}_{min}, which guarantee the existence of a margin of negotiation and therefore a possible implementation of the project, correspond to the values of α which guarantee that the social value of the project is positive. All socially desirable projects can thus be undertaken.

We have described the relationship between the terms of the contract, the expertise and the effort of the biobank. Until now, this analysis has focused solely on the problem of the *participation* of the different actors. We now turn to the problem of moral hazard linked to the non-observability of effort, i.e. to the problem of *incentivizing* effort.

II.C Effort, Contracts and Expertise

We know the conditions under which a biobank accepts the request of the research unit. When the biobank's effort can be specified in the contract, the royalty rate and fixed transfer are equivalent instruments. When the effort cannot be specified in the contract, the biobank will only exert effort if it serves its interests. Royalty rates and transfers are no longer equivalent: only a royalty rate that leaves all the value of the innovation to the biobank allows the socially optimal level of effort. The following chart shows (for a fixed transfer F) the relationship between the minimum royalty rate (r^{e}_{hm}) that solves the moral hazard problem (making it possible to guarantee the effort) and the expertise of the biobank.



The problem of moral hazard makes the exercise of effort less common, but allows the

biobank to obtain a strictly positive utility. Indeed, let us assume that the research unit proposes the royalty rate r^e_{min} to the biobank. By definition, the value for the biobank of participating in the project is zero if it exerts effort. It can agree to participate. However, since the effort is not observable, the biobank prefers not to exert effort because, at this r^e_{min} rate, the value for the biobank of participating in the project without exerting effort is strictly positive. A higher minimum royalty rate r^e_{hm} must therefore be proposed to the biobank so that it **prefers** to make the effort ($r^e_{hm} > r^e_{min}$). Even if all bargaining power is in the hands of the research unit, the value of a project undertaken by a sufficiently experienced biobank is therefore strictly positive.

Effort is socially efficient as soon as the expertise of the biobank is greater than α^e_{min}. Effort is made by a biobank of this expertise level only if it receives all income from innovation *(r=1)*. At this rate, the research unit receives no income from innovation and prefers that the biobank does not exert effort. The possibilities of effort are then restricted relative to the social optimum. Effort will be possible only if the biobank's level of expertise is greater than α^e_{hm} (where $\alpha^e_{hm} > \alpha^e_{min}$): there is under-provision of effort.

II.D What level of expertise?

The above analysis demonstrates the importance of the expertise level. This raises the question of the optimal level of expertise from the perspectives of the research unit and the biobank.

The research unit selects a biobank according to two important elements: the probability that its project will be accepted, and its expected value if accepted. Given that its project is accepted, it has been shown that the research unit prefers the highest possible level of expertise: the value of the project for the research unit strictly increases with the level of expertise, even if the cost of sample production increases with the level of expertise. As for the decision to allocate samples, a more experienced biobank is more selective (hypothesis H1): the probability that the project is accepted decreases with the expertise of the biobank. We can show that the first effect always dominates the second: the research unit always prefers the most experienced biobank.

We have previously shown that only projects carried out by the most experienced biobanks ($\alpha \geq \alpha^e_{hm}$) guarantee a strictly positive profitability. We can show that this minimum profitability can decrease with the level of expertise. This unintuitive result stems from the fact that an increase in expertise has several effects on the minimum profitability of the biobank. More expertise increases the success of the innovation and therefore the profitability of the biobank. But more expertise allows a lower minimum royalty rate r^e_{hm}, which reduces the profitability of the biobank. This second effect may outweigh the first: the highest minimum profitability can be obtained by the biobank with α^e_{hm} expertise.

The minimum profitability may decrease with the level of expertise but we know that more expertise offers a higher bargaining power, so the outcome of negotiation can be more favorable when the biobank is more experienced.

III. Economic Challenges of Networking

Expertise also plays a fundamental role in the decision of a biobank to participate in a network and share the fruit of its work with other biobanks.

Consider a referring biobank charged with reviewing the research unit's request. What is the social value of additional expertise for this biobank? Additional expertise can bring value to the project if it sometimes allows the referring biobank to be persuaded that it has made a mistake in deciding whether to provide samples or that it has made a mistake in its decision to get involved in the project. A necessary condition for participation of a second biobank in the project is therefore that this participation increases the success of innovation or increases the income from innovation.

Clearly, an inexperienced biobank derives benefits from this network: it can access a larger number of projects and participate in more ambitious projects if it can associate itself with a biobank of greater expertise. Its collaboration with specialized biobanks also allows it to increase its expertise, which in the long term has a socially positive effect on the quality of innovation (Tykvova (2007)). On the other hand, it is more difficult for a very experienced biobank to associate with an inexperienced biobank insofar as the contribution of this biobank to the project has a lower social value than its own (Casamatta and Haritchabalet (2007)).

Moreover, this association worsens the problem of moral hazard. Getting both biobanks to exert effort is more difficult. Each biobank benefits from the other's effort. A biobank can then seek to reduce the cost of its effort by choosing a lower level of effort. This free-riding behavior exacerbates the under-provision of effort. We have shown that expertise is important to ensure effort. A more experienced biobank will thus be more concerned with the free-rider problem.

Thus, while an inexperienced biobank only derives benefits from participating in a network, a highly experienced biobank will essentially bear the costs (linked to information asymmetries) and will be reluctant to join a network.

IV. Public policy recommendations

The highlights of the relationship between the biobank and the research unit, and their implications, are presented below.

a. A simple pricing rule allows socially optimal sample production: the sample tariff must be strictly lower than the marginal cost of production. This tariff depends only on the biobank's marginal cost of production. Price discrimination according to the public or private nature of the research unit is therefore irrelevant.

b. A high level of expertise offers a greater margin of negotiation and is always valued by research units.

c. Only a biobank that is sufficiently experienced and exerts effort can achieve a strictly positive minimum profitability. Above a certain level of expertise, a costly strategy to increase expertise may not be relevant: a biobank cannot reap the benefits of its investment.

d. Networking is more easily accepted by generalist biobanks.

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