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EXPERTISE
IN THE RELATIONSHIP BETWEEN
BIOBANKS AND
RESEARCH UNITS

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Expertise in the relationship between biobanks and research units

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Abstract

We propose to model the relationship between a biobank and a research unit and we 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 biological 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. We show that 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. A high level of expertise offers a greater margin of negotiation and is always valued by research units. 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.

Keywords: innovation, licences, expertise, moral hazard

JEL Codes : O31, L14, D23

1 Introduction

Biobanks are service-provider infrastructures that offer access to biological resources for academic and industrial researchers. These centers make samples available to researchers, allowing them to test hypotheses and develop innovations. This research helps to improve the diagnosis and therapeutic management of patients. Biological samples are the essential input for the success of this innovation. The management of these biological resources requires considerable scientific and technical expertise. Biobanks must comply with numerous legal and regulatory requirements, particularly concerning the collection and transport of samples and the management of personal data. This data represents all the information that relates to the sample and that allows its use in the best conditions. One of the difficulties for biobanks is to master the collection of this information. Sample production requires a great deal of coordination between various professions to produce a high-quality input. The problem of economic valorization of biobanks is thus mainly a problem of valorization of innovation: the biobank produces samples that serve as inputs for public or private research units. The success of innovation is highly dependent on the quality of the samples and on the degree of involvement of the various agents in the sample production chain. When providing samples, the activity of biobanks is potentially characterized by a significant problem of information asymmetries in its relationship with the innovator. The problem of economic valorization of inputs in the innovation process in the presence of information asymmetries has been studied in the economic literature. Many authors have analyzed what the contract between the different parties should be to obtain adequate remuneration for the effort and maintain incentives for innovation (Aghion and Tirole (1994), Tirole (1999)). In particular, these contracts call for distribution of innovation property rights between the different parties, and for payment of licenses and royalties.

Certain specificities of the activity of biobanks nevertheless require a focused economic analysis. Several biobank decisions affect the organization of input supply and thus determine the market for biological samples. These

decisions may concern the strategic positioning of a biobank and determine the way it fits into the national and international landscape. They may also affect the operational functioning of the biobank. Thus, in addition to the multiplicity of agents for whom incentive compensation must be provided, the choice of the number of collections and samples is a decision variable that determines the specialized or generalist character of the biobank. The decision to network several biobanks is also crucial for the success and quality of innovation.

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. 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.

2 The model

We propose a theoretical analysis of the relation between a biobank and a research unit.

We consider a research unit aiming at investing an amount I for the development of a new drug whose profitability is uncertain. This project requires biological material stored in a biobank, i.e. a research infrastructure collecting and annotating a large number of biological samples. The provision of such a collection incurs both a variable and a fixed cost.

We assume that the research unit addresses a demand for a number of x samples. The project is innovative : it can either succeed (revenue $R(x)$)¹ or fail (revenue 0). The probability of success depends on the quality of the project. If the project is good, the probability of success is p_h ($1-p_h$ is the probability of failure of a good project). If the project is bad, the probability of success is $p_l < p_h$. We assume that only good projects are profitable :

$$p_h R(x) > I > p_l R(x).$$

The true quality of the project is initially unknown. We denote q_0 the a priori probability that the quality of the project is good.

The research unit must obtain a specific agreement from the biobank to have access to the biological material. We denote BE the biobank's expert in charge of the biological material and the associated data. The decision is the hand of the biobank expert : a review process yields to either a reject or an acceptance of the project. We indeed assume that the review process

¹The revenue R is a concave function of x .

generates a signal related to the project true quality. For simplicity, we assume that generating this signal is costless. This signal can be either good ($s = H$) or bad ($s = L$) and is all the more precise that the expertise of the *BE* is high. In other words, all *BEs* have the ability to screen projects, but they have different levels of observable ability. This assumption captures the idea that some patricians may be more experienced than others. Formally, the signal s received by a *BE* with expertise α has the following properties:

$$\begin{aligned} \text{prob}(s = H/p_h) &= \alpha, \\ \text{prob}(s = L/p_l) &= \alpha, \end{aligned}$$

where $\alpha \in [\frac{1}{2}, 1]$. The probability of receiving a good signal conditional on a project being good increases with the *BE's* expertise. After observing a signal, the *BE* updates his belief on the project's quality using Bayes' rule. We assume that biobanks are sufficiently experienced so that a project receiving a positive (negative) evaluation is (not) socially desirable. Were this not true, biobank expertise would be useless.

If a biobank accepts the project, a period of development follows in which the expert can decide to support or not the research unit. We indeed consider that the role of the biobank expert is not only crucial for the screening of projects but also in the development of the project. We assume that *BEs* can use their expertise to provide advice once the project has been accepted. We thus assume that patricians can exert an effort that increases the probability of success of the project, if the true quality is good. To keep things simple, there are only two possible levels of effort. If the expert exerts effort (decision $e = 1$), he incurs a private cost $c_e > 0$ and increases the probability of success of a good project by $\epsilon > 0$ (the probability of success of a bad project remains unchanged). If the expert does not exert effort (decision $e = 0$), the probability of success remains unchanged.

These assumptions yield to the following probability that the project succeeds

$$p^s(e, \alpha) = [q_s(p_h + \epsilon \mathbf{1}_{e=1}) + (1 - q_s) p_l].$$

We can then define the social value of a project as

$$V_\alpha^s(e) = p^s(e, \alpha)R(x_\alpha^*(e)) - (c_x + \alpha)x_\alpha^*(e) - c_e \mathbf{1}_{e=1} - F - I, \quad (1)$$

where $c_x + \alpha$ is the unit cost of each sample², F represents the fixed cost of the biobank and x is set at the optimal number of samples $x_\alpha^*(e)$.

This optimal number $x_\alpha^*(e)$ must verify that marginal benefit of a sample equals its marginal cost :

$$p(e, \alpha)R'(x_\alpha^*(e)) = c_x + \alpha.$$

It has the following properties

Lemma 1 *This optimal number $x_\alpha^*(e)$ is increasing with α and e .*

An increase in e increases the marginal benefit of a sample so that $x_\alpha^*(e)$ increases. An increase in α modifies both the marginal benefit and the marginal cost but the final effect on $x_\alpha^*(e)$ is non ambiguous.

Following our claim that biobanks play a central role in selecting and supporting project, we impose the following assumptions:

Assumption 1 *Biobank expertise is fundamental*

- *Bad evaluations should always terminate projects*

$$V_\alpha^l(e) < 0 \quad \forall \alpha \leq 1$$

- *Good evaluations are not sufficient to keep project*

$$\exists \underline{\alpha}(e) \in [0, 1] \text{ such that } V_{\underline{\alpha}(e)}^h(e) = 0.$$

Assumption 2 *Effort is not very efficient*

$$\underline{\alpha}(0) < \underline{\alpha}(1)$$

²We assume that the marginal cost of each sample increases with the expertise of the biobank.

Assumption 1 says that a sufficient level of expertise is necessary to screen project. Assumption 2 ensures that it is sometimes optimal not to exert effort (otherwise, the decision to give samples would immediately trigger effort).

We now determine the payoff of the research unit and the biobank of an accepted project. For this, we need to define how the project value is shared among the two agents. We consider a standard licence contract specifying a royalty rate r (fee per unit of output) and a fixed fee T to which we add a unit price for each sample p_x . Participation constraints require that both agents obtain a non negative expected payoffs. A project will be then implemented only if V_α^{BE} and V_α^{RU} are positive, where

$$V_\alpha^{BE}(e, r, T, p_x) = p^h(e, \alpha)R(x(r)).r + (p_x - c_x - \alpha)x(r) - c_e \mathbf{1}_{e=1} + T - F \quad (2)$$

and

$$V_\alpha^{RU}(e, r, T, p_x) = p^h(e, \alpha)[R(x(r))(1 - r)] - p_x x(r) - T - I. \quad (3)$$

Observe first that $0 \leq V_\alpha^{BE}(e, r, T, p_x) + V_\alpha^{RU}(e, r, T, p_x) \leq V_\alpha^h(e)$ (with the equality when $x(r) = x_\alpha^*(e)$), this implies that all accepted projects are socially desirable. We are then concern with an insufficient innovation problem. Also, we know that licence agreements (a positive royalty rate) result into an insufficient level of effort. Here, we can observe that the royalty rate also impacts the choice of the number of samples.

We now investigate more precisely how the combination of these contract and the biobank expertise impacts the innovation success.

2.1 How to price samples?

A contract with a strictly positive royalty rate and sample price distorts both the marginal benefit and cost of the sample of the the biobank and the research unit. This implies in particular that the biobank and the expert may disagree on number of samples. Lets define $x_{RU}^*(e)$ as the number of samples that maximizes the research unit payoff and $x_{BE}^*(e)$ as the number of samples that maximizes the biobank payoff. We have

$$p^h(e, \alpha)R'(x_{RU}^*(e))(1 - r) = p_x$$

$$p^h(e, \alpha)R'(x_{BE}^*(e))r = c_x + \alpha - p_x.$$

Lemma 2 *Comparative statics show that*

- x_{RU}^* decreases with the royalty rate r , increases with the biobank expertise α and the level of effort.
- x_{BE}^* crucially depends on the gap between the price and the marginal cost. x_{BE}^* increases (decreases) with the royalty rate, the biobank expertise and the level of effort if the sample price is greater (lower) than the marginal production cost.

Each agent selects a number of samples such that its marginal benefit equals its marginal cost. Compare to the social optimum, the marginal benefit decreases for the two agents (who share the revenue in case of success) which tends to decrease the demand of samples. The marginal cost is p_x for the research unit and $(\alpha + c_x - p_x)$ for the biobank. When $p_x = 0$, all the costs are left to the biobank : the research unit selects an excessive number of samples whereas the biobank selects an insufficient one. When $p_x = \alpha + c_x$, all the costs are left to the research unit who selects an insufficient number of samples. When $p_x > \alpha + c_x$, the marginal benefit of a sample increases for the biobank which results in an excessive production of samples. The excessive production result is more important when the biobank has a low expertise and does not exert effort. A low royalty rate enhances this effect.

We can however restore the social optimum, whatever the agent in charge of selecting the number of samples and whatever the level of effort.

Proposition 1 *There exists a price $p_\alpha^* = (\alpha + c_x)(1 - r) < (\alpha + c_x)$ such that $x_{BE}^*(e) = x_{UR}^*(e) = x_\alpha^*(e)$.*

It is socially optimal to price samples at their marginal cost revised at the royalty rate. Agents must share the marginal cost up to the royalty rate.

The biobank must support part of the variable production cost. Observe also that the price is the same whatever the level of effort.

In the following of the paper, we assume that $p_x = p^* = (\alpha + c)(1 - r)$ such that all agents agree on the socially optimal number of samples x^* .

Project values then rewrite

$$V_\alpha^{BE}(e, r, T) = rp^h(e, \alpha)[R(x_\alpha^*(e)) - (c_x + \alpha)x_\alpha^*(e)] - c_e \mathbb{1}_{e=1} + T - F \quad (4)$$

and

$$V_\alpha^{RU}(e, r, T) = (1 - r)p^h(e, \alpha)[R(x_\alpha^*(e)) - (c_x + \alpha)x_\alpha^*(e)] - T - I. \quad (5)$$

2.2 License contract and expertise

We first illustrate the relation between project values, level of biobank expertise and royalty rate by representing the minimum (maximum) royalty rate such that the value of the project be positive for the biobank (the research unit) for a given transfert T . We denote $\underline{r}^{BE}(e, T)$ the royalty rate satisfying $V_\alpha^{BE}(e, \underline{r}^{BE}(e, T), T) = 0$ and $\bar{r}^{RU}(e, T)$ the royalty rate satisfying $V_\alpha^{RU}(e, \bar{r}^{RU}(e, T), T) = 0$.

Assumption 2 implies that $\underline{r}^{BE}(0, T) \leq \underline{r}^{BE}(1, T)$: exerting effort requires a higher royalty rate. Also, the research unit can accept to increase the royalty rate if the biobank exerts effort ($\bar{r}^{RU}(0, T) \leq \bar{r}^{RU}(1, T)$).

Exchange is possible if $\underline{r}^{BE}(0, T) \leq \bar{r}^{RU}(0, T)$, and a necessary condition for effort is that $\underline{r}^{BE}(1, T) \leq \bar{r}^{RU}(1, T)$. The following graph represents these royalty rates as a function of α together with the minimum socially optimal expertises $\underline{\alpha}(0)$ and $\underline{\alpha}(1)$ defined in assumption 2.

Proposition 2 *It exists $\underline{r}(e, T)$ decreasing with α and increasing with e such that*

$$V_{\underline{\alpha}(e)}^{RU}(e, \underline{r}(e, T), T) = V_{\underline{\alpha}(e)}^{BE}(e, \underline{r}(e, T), T) = V_{\underline{\alpha}(e)}(e) = 0$$

We know that all accepted projects are socially desirable, proposition 2 implies that all socially desirable project can be implemented. Both agents

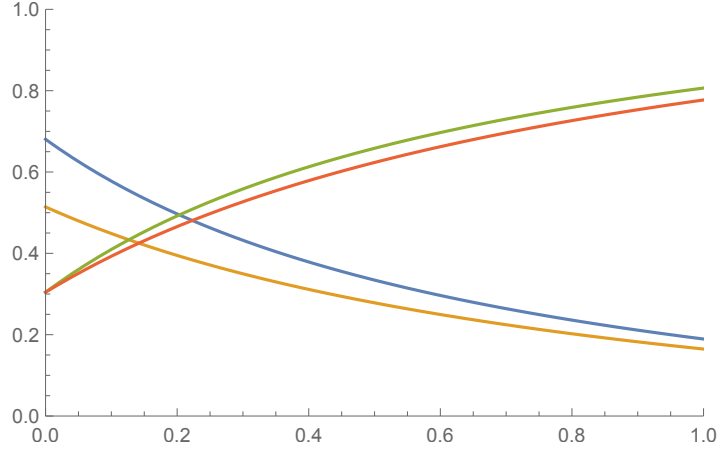


Figure 1: Minimum and maximum royalty rates and expertise

can negotiate a royalty rate between $\underline{r}^{BE}(e, T)$ and $\bar{r}^{RU}(e, T)$. This negotiation region increases with the biobank expertise.

Alternatively, we can illustrate the relation between the project values, the level of biobank expertise and the fixed fee T by representing the minimum (maximum) fixed fee such that the value of the project be positive for the biobank (the research unit) for a given royalty rate r .

We denote $\underline{T}^{BE}(e, r)$ the fixed fee rate satisfying $V_{\alpha}^{BE}(e, r, \underline{T}^{BE}(e, r)) = 0$ and $\bar{T}^{RU}(e, T)$ the royalty rate satisfying $V_{\alpha}^{RU}(e, \bar{r}^{RU}(e, T)) = 0$. The following graph represents these fixed fees as a function of α together with the minimum socially optimal expertises $\underline{\alpha}(0)$ and $\underline{\alpha}(1)$ defined in assumption 2.

Proposition 3 *It exists $\underline{T}(e, r)$ decreasing with α and increasing with e such that*

$$V_{\underline{\alpha}(e)}^{RU}(e, r, \underline{T}(e, r)) = V_{\underline{\alpha}(e)}^{BE}(e, r, \underline{T}(e, r)) = V_{\underline{\alpha}(e)}(e) = 0$$

Again, all socially desirable projects can be implemented. The negotiation region increases with the biobank expertise.

This section describes the relation between project values, licence contract and expertise for a given level of effort. We have abstracted from moral

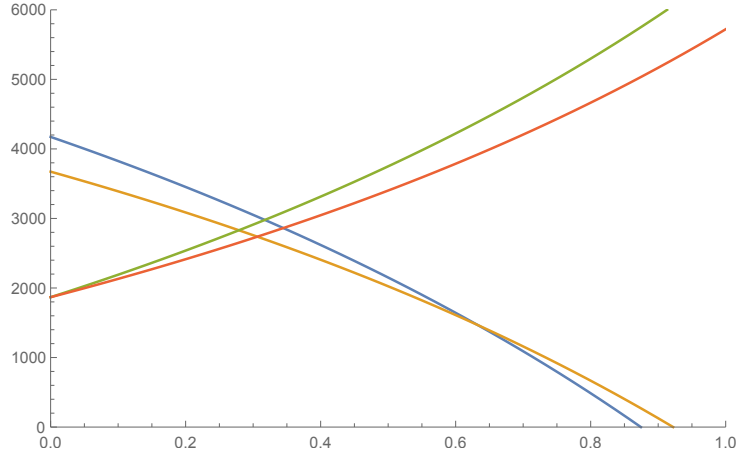


Figure 2: Minimum and maximum fixed fees and expertise

hazard problems due to the non contractibility of effort. We explore this issue in the next section.

2.3 The effort decision

Assume now that effort is non contractible and consider that the research unit has all the bargaining power so that he is able to impose the minimum royalty rate $\underline{r}^{BE}(e, T)$.

We know that the biobank accepts the project if $V_\alpha^{BE}(0, r, T) \geq 0$ and prefers to exert effort when $V_\alpha^{BE}(1, r, T) \geq V_\alpha^{BE}(0, r, T)$.

The decision to exert effort is obviously related to the royalty rate. Assume that the biobank obtains the minimum royalty rate $\underline{r}(1)$, we have $V_\alpha^{BE}(1, \underline{r}(1), T) = 0 < V_\alpha^{BE}(0, \underline{r}(1), T)$ and effort is never exerted. The biobank accepts to exert effort only when the royalty rate exceeds $\underline{r}^e > \underline{r}(1)$ where r^e is defined by

$$V_\alpha^{BE}(1, \underline{r}^e, T) = V_\alpha^{BE}(0, \underline{r}^e, T) > 0.$$

The research unit will prefer effort only if the biobank is sufficiently expertised as illustrated on the following graph.

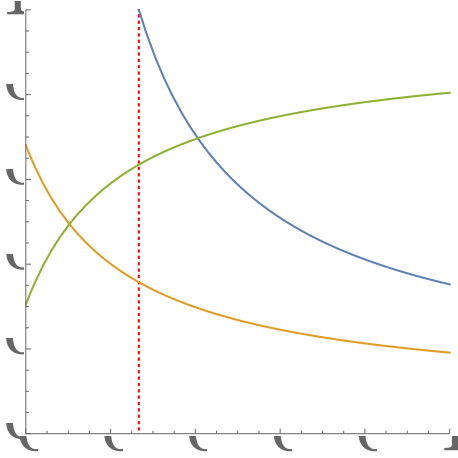


Figure 3: Royalty rate and effort

The vertical dotted line is the level of expertise such that exerting effort is efficient. The blue curve is the minimum royalty rate \underline{r}^e such that the biobank prefers to exert effort. The green curve is the maximum rate such that the research unit prefers the effort. A sufficient condition to observe effort is that $\underline{r}^e \leq \bar{r}^{RU}(e, T)$.

These results can be summarized in the following proposition.

Proposition 4 *Only highly expertised biobanks with $\alpha \geq \underline{\alpha}^e$ exert effort and obtain a strictly positive rent. The biobank rent decreases with α .*

The following graph represents both agents' payoffs when $r = \underline{r}^e$ as a function of α . The yellow line is the research unit payoff : it is increasing with α and positive when $\alpha \geq \underline{\alpha}^e$. The blue line is the payoff of the biobank exerting effort and obtaining the minimum royalty rate \underline{r}^e . Indeed, an increase in the expertise level has two opposite effects on the biobank payoff: an increase in the probability of success and a decrease in the minimum royalty rate \underline{r}^e . The second effect dominates so that the highest possible minimum payoff is obtain with an expertise level $\underline{\alpha}^e$.

The minimum profitability may decrease with the level of expertise but we know that more expertise offers a higher bargaining power, so the outcome

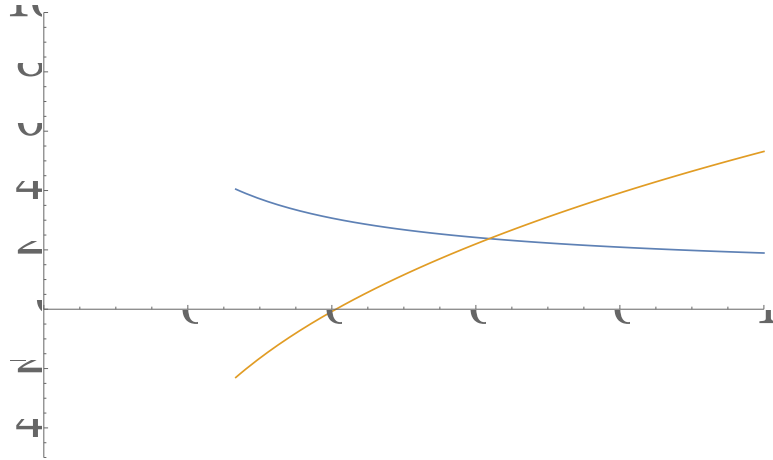


Figure 4: Payoffs with effort

of negotiation can be more favorable when the biobank is more experienced.

2.4 Which biobank?

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.

The research unit must select the level of expertise that maximizes its expected payoff. The research unit must also take into account the probability that its project be accepted. The research unit faces an efficiency rent

trade-off. The value of the project as the rent left to the CRB increases with α .

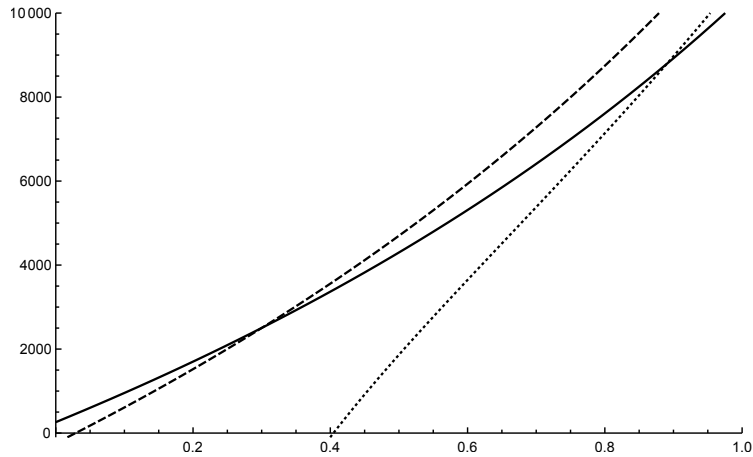


Figure 5: Expertise UR

Assuming the minimum royalty rate, the value of the project is always increasing with α . The dotted line is the project value when the biobank exerts effort : effort is demanded only for highly experimented biobanks.

Consider now the decision to accept to give samples : an experimented biobank is more selective. Denote $q(\alpha)$ the probability that a projected is accepted. The research unit must choose α such that the ex-ante expected value of the project is maximum. Our model specification yields the same conclusion that the project value increases with α .

3 Conclusion

The paper highlights the relationship between the biobank and the research unit. We find that 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. A high level of expertise offers a greater

margin of negotiation and is always valued by research units. 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.

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