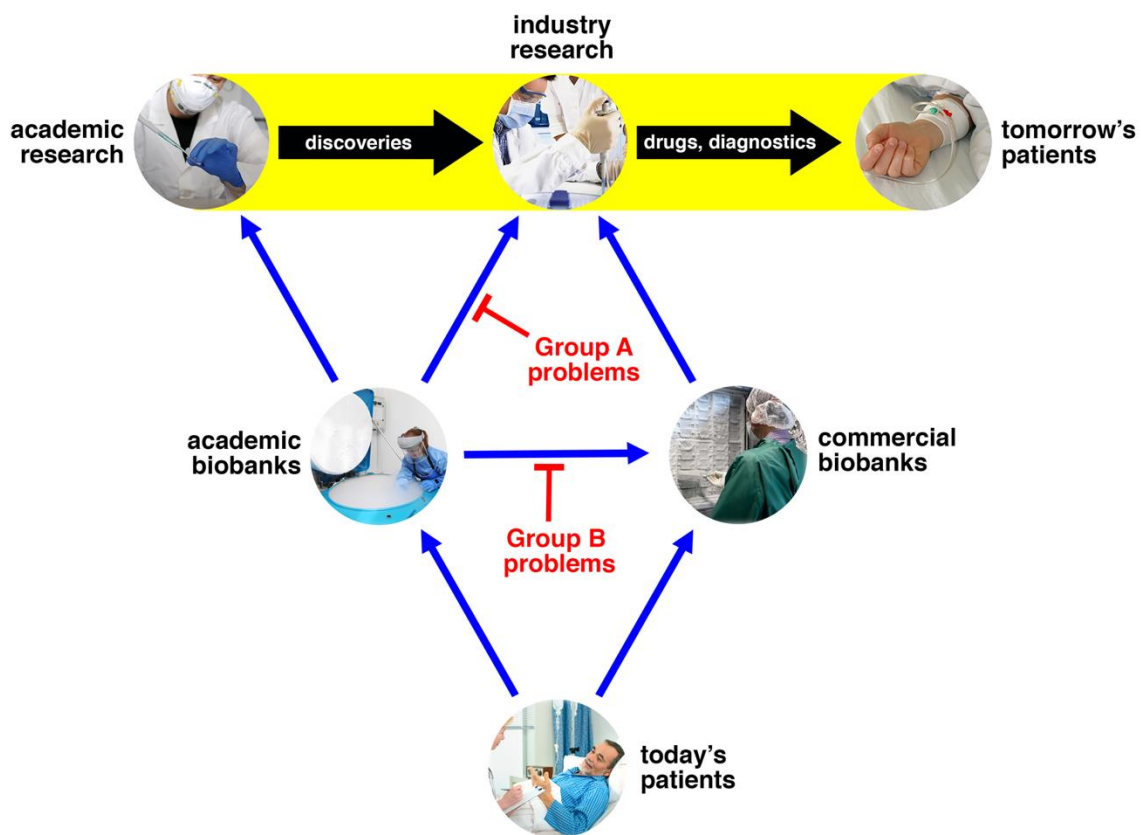


# 10. Biosample Supply Problems Affecting Industry Research And Tomorrow's Patients

## Different Stakeholders With Different Perspectives



Everybody agrees that medical research is important and wants to support it, but biobank stakeholders and regulators must consider other priorities as well. Patients who donate their biosamples want to be sure that their donations are used in ways they find acceptable. Biobank managers need to run sustainable operations, not only financially sustainable, but also sustainable in operational and social dimensions ([Watson et al. \(2014\)](#)). Academics who set the policies for academic biobanks, need to demonstrate that the academic productivity, particularly in terms of the publication metrics of their institution. Ethics committee members who oversee the research use of biosamples, need to safeguard the interests of patients. Lawmakers who decide the regulations for use of human tissue need to develop coherent rules and consider the full picture of how human body parts may be used in all contexts. Researchers who add to our understanding of disease processes and who discover and validate

new drugs and biomarkers need a supply of suitable biosamples. They include researchers in academia and also researchers in industry. In this setting, industry includes not only large pharmaceutical companies, but also much smaller and more numerous biotechnology companies which (1) we depend on for innovation and (2) may have the biggest problems in terms of biosample access (See LinkedIn article on [Biosample Needs of Different Industry Players](#)).

With all these different stakeholder interests, it is clear that biosample supply must be carefully regulated and not surprising that major biosample supply problems do exist. Nevertheless, all the different stakeholders need to remember that overcoming these biosample supply problems is vital for tomorrow's patients.

## **Why The Biosample Needs Of Industry Are Important**

What many people may not realise is that without the involvement of industry researchers, no medical research will ever put new drug and diagnostic products into the hands of patients and their caregivers. Only industry has the necessary funds, expertise and experience to take a potential product from the laboratory bench to market. So just like academic researchers, industry researchers need a supply of biosamples to do their vital work. For an academic biobank to supply researchers in industry, there are many problems to be overcome (see group A and B problems in the diagram above and described below). As a result, industry researchers often depend on commercial biobanks to provide them with the biosamples they need.

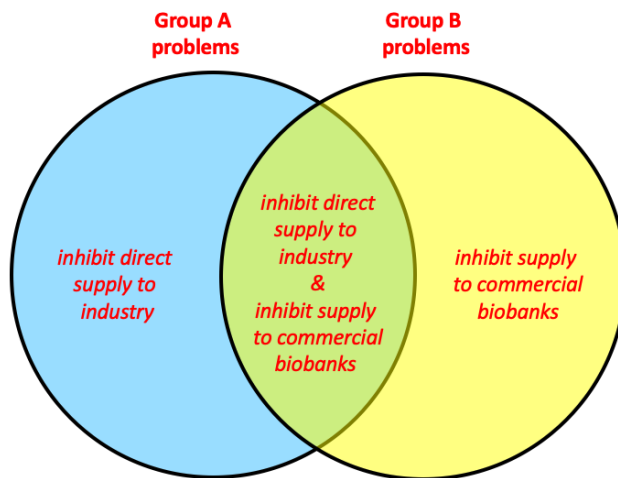
## **Why Commercial Biobanks Are Needed**

In general, the academic world sees commercial biobanks as outsiders, and may view them with suspicion because of their for-profit nature. Nevertheless, commercial biobanks play an important role and exist for a good reason: industry researchers need commercial biobanks to supply them with biosamples. If it were easy for industry to obtain these samples from academic biobanks, there would be no need for commercial biobanks.

	<b>Academic Biobanks</b>	<b>Commercial Biobanks</b>
<b>Strengths</b>	<p>Emphasis on sample quality.</p> <p>Ready access to extensive reliable clinical information.</p> <p>Greater awareness of research applications.</p> <p>Much more numerous than commercial biobanks in many higher income countries.</p>	<p>Vast networks of requesters in industry.</p> <p>Vast networks of biosample providers.</p> <p>Ability to access samples in low-income countries where academic biobanks do not exist.</p> <p>Accustomed to working fast, in line with industry timelines.</p> <p>Well established and well accepted in the USA</p>
<b>Weaknesses</b>	<p>Lack of funding.</p> <p>Lack of awareness of industry biosample needs.</p> <p>Unaccustomed to working fast, in line with industry timelines.</p> <p>Contractual processes and ethical approvals can take too long for industry.</p>	<p>Lack of support from many academic biobanks.</p> <p>Lack acceptance in some countries.</p> <p>Lack of provenance information in some cases</p>

As shown in the table above, academic biobanks and commercial biobanks have different strengths and weaknesses. If academic biobanks and commercial biobanks were to work together and combine their strengths there would be benefits to both sides. In particular, academic biobanks would gain much needed funding on a fee-for-service basis. Commercial biobanks would receive many more useful samples from geographically relevant areas. Most importantly, medical research across industry would be much better served.

## How Academic Biobanks Can Supply Industry



Academic biobanks can supply industry directly, or indirectly via a commercial biobank.

Problems that affect direct supply are considered here as group A problems. Problems that affect indirect supply are considered as group B problems. There is a lot of overlap between the two groups.

### Group A-Specific Supply Problems

1. **'Match-making' difficulty.** It is often very difficult for researchers in industry to identify academic biobanks that can meet their increasingly specific requirements. Similarly, it can be difficult for biobanks to identify industry partners who would be interested in the particular range of biosamples they can offer. This is a major reason why there is a need for commercial biobanks, since in addition to large inventories of samples they may have large networks of industry clients and biosample providers. Commercial biobanks are certainly experts at 'match-making' and have current, detailed, experience-based knowledge that can not always be found in the biobank directories offered by various organisations.

### Group B-Specific Supply Problems

Commercial biobanks vary from one to another. In some cases there may be the following issues:

1. **Lack of traceability and provenance information.** Traceability of samples is important for both scientific and ethical reasons (see LinkedIn article: [Why Researchers Must Know Biosample Provenance](#)). For business reasons, some commercial biobanks limit the amount of information they provide on the origin and destination of biosamples, which presents problems to the end-users and providers respectively. Commercial biobanks may collect samples all over the world, not only in higher income countries like the USA but also in many less developed countries where ethical oversight may not be as firmly maintained. As a result, the clients of the commercial biobank need to demand provenance

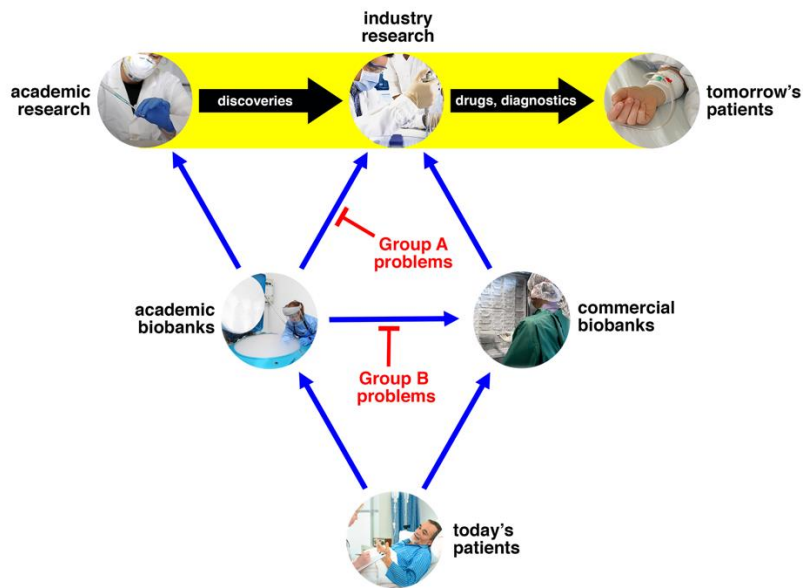
information about samples supplied and the commercial biobanks need to provide convincing evidence that their samples were collected with appropriate consent and ethical oversight.

2. **Lack of pricing transparency.** Academic biobanks may sometimes want to know the fee for service that the commercial biobank charges the industry requester, for internal reporting purposes. This information may or may not be available.

## Supply Problems Belonging To Both Groups A & B

1. **Tight industry timelines and deadlines.** This is a fact of life in industry. Biobanks and institutions that want to provide samples to industry by whatever route, need to adapt accordingly.
2. **Highly specific sample requests from industry.** Again, this is another fact of life: sample requests are becoming increasingly specific. Often the only answer is for the biobank to collect samples prospectively in order to fulfil a request.
3. **The demands of academic biobanks may be unacceptable to industry.** If an academic biobank sets research collaboration with joint publications as a condition for supply, this is very often not possible, because companies in industry need to protect intellectual property in order to survive. Hopefully, more academics will start to regard the supply of biosamples to support industry projects, as a valuable contribution and achievement in itself. Some academic biobanks have set the level of supply to industry as a key performance indicator, which seems a very positive move.
4. **Various social, ethical and legal concerns.** Concerns about patient attitudes to collaboration with industry, risks of commodification of human biosamples, and questions about the acceptability of fee-for-service transactions may discourage academic biobanks from supplying samples to industry. In other articles on LinkedIn, the following arguments are presented:
  - If members of the public do not support industry research on their biosamples, it may be that they do not understand the potential benefits. In this case the appropriate action is to provide education. See: [Ensuring Public Support for Biobank Cooperation With Industry](#)
  - Modern biobanks treat human biosamples with extraordinary respect, paying close attention to informed consent, ethical oversight and data protection. Risks of commodification are therefore greatly reduced. See: [What is Commodification?](#)
  - The Oviedo convention (which applies in those European Community member states in which it has been ratified), allows that reasonable fees may be charged to cover the cost of sample processing. Therefore, biosample transactions are not prohibited in these countries. See: [Acceptable Transactions in Biobanking](#). At the same time, it is important for biobanks to be able to demonstrate that the fees charged for sample supply are simply to cover the cost of sample processing. Laws against buying and selling biosamples exist in many countries and in some cases the penalties for making profit from biosample transactions can be severe. See [Singapore Biomedical Research Act](#).

## Conclusion



This has been a quick summary of the biosample supply problems affecting academic biobanks, commercial biobanks, and industry. Yes, there are many different stakeholder interests. Yes, there are many problematic issues. But one thing is crystal clear: overcoming biosample supply problems is vital for tomorrow's patients. So we need to keep the top line of this diagram (highlighted in yellow) at the forefront of our minds. For new drugs and diagnostics to reach tomorrow's patients it is essential for researchers in academia and industry to be supplied with the necessary biosamples.

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Disclaimer: the author of this article works independently and any views expressed are his own.

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