

Finding Your Ideal Research Partner

The Essential Outsourcing Decision Guide

When should you outsource cellular immunity assays?

Increasingly, companies and even academics are finding that outsourcing partnerships allow them to save time, mitigate risk, and achieve a competitive advantage in the race to the next big breakthrough. As technology advances, the only way to keep up has become to recruit expert service providers. They will have performed the lengthy optimization and validation that a complex process requires, which gives you the freedom to take advantage of their knowledge and focus internal resources on your core competencies.

What can I gain from outsourcing?

The advantages for you are improved company focus and efficiency, reduced overheads, and the option to be more flexible in your staffing strategy. You can also consider on-site outsourcing - bringing in an expert to your company on secondment to train up your staff and oversee a particular project.

A common prompt to outsource can be requirement for a new type of data. A PI from the product safety group of a major biotechnology company told us about his recent decision to outsource part of a study. "We needed to provide data to support safety

on a product that was beyond what we'd normally supply to a regulatory agency."

In summary, decide what you want to focus on in-house to take best advantage of your resources and staff skills, and then consider the benefits of outsourcing the remainder.

It is natural to have concerns about a new way of working. However, the right partner company will work with you to address any initial worries so that you are able to integrate them into your research strategy as smoothly as possible. It's a good idea to think about outsourcing as early as you can in the study design process – so that it can become part of your approved study protocol.

Why Outsource?



In a study conducted by The Outsourcing Institute¹, the top five reasons to outsource proved to be

- 1) Reducing and controlling operating costs
- 2) Improving company focus
- 3) Gaining access to world-class capabilities
- 4) Freeing up resources for other purposes
- 5) Accessing resources not available internally

¹ www.outsourcing.com

Finding an outsourcing partner

There are various strategies for this – larger companies may have a list of pre-approved partners, others may wish to keep their options flexible, to enable them to take advantage of emerging technologies as a project demands. As outsourcing becomes more mainstream, some companies even retain dedicated prospecting teams to find the best suppliers.

At DSTL (Defence Science and Technology Laboratory, UK), Lyn O'Brien advertized her work requirement when she needed information on the T cell response to chimeric and humanized versions of her therapeutic antibody. She offers this advice:

“Make your work requirement (request for proposal) as detailed and specific as possible, so that companies can discern whether they are capable of carrying out the work”.

Business partnering events can be another excellent way to meet potential collaborators, as contract research organizations and service providers often make time to attend these events. Short meetings allow you to outline your requirements to see if you are a ‘good fit’.

Have a thorough vendor selection process

First of all, ensure that you are comparing like with like. Have any of the bidders tried to ‘upsell’ and include services that you don’t require? Can all your bidders deliver the same quality and level of service? Price is important, but should not be your only consideration.

Track record is significant: assess the reputation of your potential suppliers, and ask them for

references if they have performed a comparable project before. They should at least be able to supply you with data generated in-house, such as a sample report, so that you can get a feel for the quality and format of their data reporting.

Are the potential vendors used to working to the standard required by regulatory agencies and able to conform to standards such as ISO, and GLP and GCP if required?

In some instances, it may be most appropriate to choose a partner company that is focused on innovation – they may be more flexible to accommodate your needs and also be more up-to-

“Make your work requirement as detailed and specific as possible so that companies can discern whether they are capable of carrying out the work”

Lyn O'Brien, Defence Science and Technology Laboratory, UK.

speed with current thinking and more proactive on your behalf.

Is the company a business that you will want to work with – is it financially strong and is the management structure stable? Do they have the resources in place, or would they have to recruit staff and source equipment or even premises for your projects? Consider any factor that could have an impact on the smooth running of your project, and look at the risks of working with your favored partner. Bear in mind that you are not only commissioning a project, but to some extent choosing new colleagues. Are you impressed with their knowledge and professionalism, and are you confident that they understand your needs?

Negotiating a contract

Be careful not to underestimate the time it will take to finalize wording that you are happy with. One client told us that “agreement on contract language was the longest bottleneck”, while another faced delays of six months caused by her “lack of personnel in-house able to deal with setting up the contract”.

There can be risks involved in outsourcing, and it is worth considering these to be sure that they are more than offset by the benefits. The expertise and service you gain from outsourcing with a good partner company should easily outweigh any potential risks.

Through outsourcing a project, you will be tied to the wellbeing of another company, and may feel that you will lose a degree of control over your work. Hidden costs, security, quality control and confidentiality can all be worries, although you should be able to address all of these concerns by working with your legal advisors to ensure that the contract with your partner company protects your interests.

Your organization will probably have a standard Master Services Agreement (MSA) template. Alternatively, your service provider is likely to have one, so you can begin to work from this template towards mutually acceptable language. An experienced partner company will provide clear and well-worded responses to your questions within a reasonable time-frame.

You may want to consider enshrining some basic project management in your service agreement, or

in the statement of work relating to a specific project. Timing of activities, including interim reports and review meetings, can have a knock-on effect on your wider workflow. Similarly, have you considered what would happen if a key scientist or manager left the company – are procedures in place for informing you of the change? Finally, be prepared to compromise, as ultimately both you and your outsourcing partner will benefit from working together.

Consider a pilot study

This is an excellent strategy for informing yourself about a partner’s capabilities without committing to a full-scale study. It may also serve to provide some preliminary information that can feed into your study design. A small project will give you a feel for any issues that could arise with a supplier, and allow you to work on them together to make sure that your bigger study is not compromised by something that a little preliminary information could have avoided.

Keep in touch

The best way to maintain a good relationship with your outsourcing partner is to keep in touch. Explain any delays on your side, and schedule regular updates so that you can follow the progress of your project. It is a good idea to insist on a single point of contact, so you can be sure of talking to someone who is familiar with you and your needs.

About ProlImmune

ProlImmune provides unique solutions for discovery, preclinical and clinical researchers seeking to understand and manage adaptive immune responses. Our outsourcing services include:

- Antigen characterization
- Immunogenicity risk management
- Cellular immunity assays (ELISpot, ICS, CFSE T cell proliferation assays and multimer staining)
- HLA tissue typing

We understand the concerns that can stop you from making the decision to outsource your research work, such as difficulty in finding the right partner, anxiety over data confidentiality, or the worry of dealing with people thousands of miles away. It is natural to have these concerns and put off making the decision. However, if you want to take your project to the next stage, or achieve a competitive advantage, outsourcing some of your assays can provide the answer.

ProlImmune will listen to your concerns and work closely with you to remove them. We are committed to helping you take your studies to success through product innovation, responsive service and focused application support, saving you time and money and reducing risk.

Since the launch of our first research services in 2006, we have developed a range of cellular immunity assays (some of which are not available anywhere else) to meet the needs of researchers. Many of ProlImmune's scientific staff are qualified to Ph.D. level, and are graduates from the nearby University of Oxford.

It's easy to meet us; throughout the year we attend partnering events for the biotech industry, and are

also to be found at scientific meetings such as the American Association of Immunologists and British Society for Immunology annual meetings. Of course we will come to your site too, for a confidential discussion with all the people involved in the project.

Our Immunology Sales Specialists will work with you to design a study that best meets your needs, consulting our laboratory teams to make sure the setup is optimal. We often find that our clients gain useful information for their study design through running a pilot study first, and we strongly encourage this.

For contract management, we have an in-house legal team, and will also retain specialist counsel as required. We pride ourselves on the clarity and efficiency of our responses to client questions, as we work to ensure that the negotiation process runs as smoothly as possible.

Once underway, each project is assigned to a member of our customer service team, who will keep in touch to provide updates regarding the running of your project. They will also arrange a post-project debrief meeting, and be on hand to answer any questions relating to your service report after the project is completed.

Details of our services are available on our website:

[Cellular Immunity Services](#)

For further information on outsourcing cellular immunity services to ProlImmune, listen to our February and November 2011 webcasts:

[Technical Webcasts on Outsourced Services](#)

Some of Our Clients



October 2011: **GlaxoSmithKline** accesses ProImmune's REVEAL® Immunogenicity System to profile the physical MHC Class II binding characteristics of a set of peptides

December 2010: **Defence Science and Technology Laboratory (DSTL)** at Porton Down, UK, collaborates with ProImmune Ltd. for the use of highly sensitive naïve T cell assays, as part of their research program.

Dr. Michael Mathis : Louisiana State University Health Sciences Center, USA

“My work focuses on the development of adenovirus-based vectors for immunotherapy of breast cancer, using mouse models of the disease. ProImmune’s REVEAL® Rapid Epitope Discovery System has provided a cost-effective method for me to screen my proteins of interest for potentially immunogenic epitopes. I have been particularly

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impressed with the service that ProImmune offers, so much so that I’ve been telling my colleagues that they too should outsource more of their routine experiments to experts in order to free up their time. It really saves time and money when one takes into account the effort needed to set up these assays in-house and then wait for results. I will definitely be using the system again to obtain further data on the hits from the first round of screening.”

Dr. Jennifer Kirchherr: Duke Human Vaccine Institute, North Carolina, USA

“We have a programme of clinical studies and it is important for our researchers to be able to correlate the immune responses they observe with HLA type. We looked at a range of companies offering tissue typing, and also at using an on-campus typing facility, and we found that ProImmune were able to offer us the best pricing and turnaround time. We now send them regular batches of samples to type. They have been wonderfully easy to work with, if we ask anything they get right back to us and overall it has been a really good experience.

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