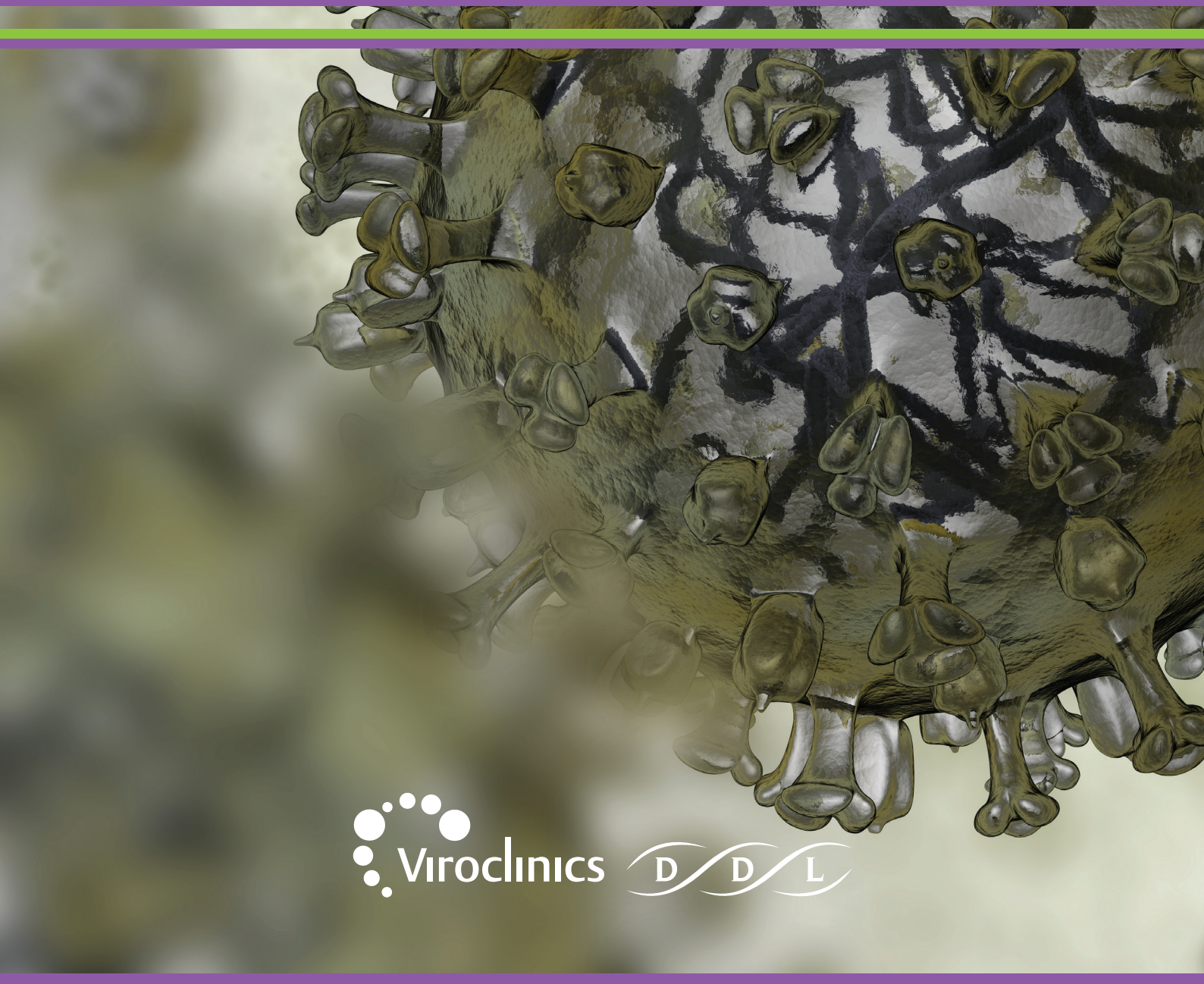
A Viroclinics Publication - 2017

Outsourcing Preclinical Vaccine Testing and Clinical Diagnostics with Confidence



Viroclinics D D L

WHITEpaper

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Contents

1. Introduction

"There is no such thing as a special category of science called applied science: there is science and its applications, which are related to one another as the fruit is related to the tree that has borne it."

Louis Pasteur[1]

Vaccines can certainly be seen as one of the low hanging fruits that Pasteur refined at the end of the 19th century. Throughout the 20th century vaccines contributed to healthcare development, prevented many deaths and yielded high profits for pharmaceutical companies. The question is: do vaccines remain low hanging fruits, throughout the 21st century? The answer is yes, but the road to successful vaccine development is not without obstacles.

Nowadays vaccine manufacturers face many challenges, even though the biotech sector's outlook remains positive with stable estimated growth rates[2] and a pipeline containing more than 300[3] vaccines. Making funding choices, regional allocation and vaccine/ disease prioritization are lengthy processes, dominated by key stakeholders and influencers, such as the World Health Organization, The GAVI Alliance and UNICEF. External market conditions are turbulent, which is reflected by the so many M&A activities in recent years[4,5]. Important questions arise in relation to M&A activity, such as: how to deal with the increased size and coordination requirements in the post M&A situation? Relevant organizations might consider to outsource processes or services that do not belong to the core competence of the organization anymore.

Ideally, outsourcing is built on two perspectives: cost efficiency and specialization. By using specialized services, the outsourcing company can increase its strategic focus. Besides cost efficiency an outsourcing contractor can add additional weight in the scale: innovation. Innovative solutions can be found in novel pre-clinical and clinical research models, supporting a swift market delivery, which is essential for both new vaccines and vaccine improvements.

This white paper explores an outsourcing partnership model as a supportive strategy for manufacturers, CROs and other key stakeholders in the vaccine development field.

Many pharmaceutical companies, including vaccine producers are now focused on the first step of the drug development process and R&D is shifting towards discovery and development of new targets rather than pre-clinical and clinical research. This makes R&D an ideal outsourcing target for vaccine producers. Safety and efficacy testing of vaccines consist of complex processes and clinical trials, involving thousands of research subjects and samples.

R&D IS SHIFTING TOWARDS DISCOVERY AND DEVELOPMENT OF NEW TARGETS RATHER THAN PRE-CLINICAL AND CLINICAL RESEARCH

2. A strategic outsourcing perspective

Over the years, pharmaceutical organizations have evolved into complex, global multi-dimensional matrix organizations with a managerial focus on coordination between functional areas, such as R&D, manufacturing and supporting activities including sales & marketing, HR and finance. Vaccine manufacturers grew rapidly because of organic growth or through merger & acquisition activities, with an increase in complexity and corporate ambiguity. Many biotech companies have started strategic realignment programs, product portfolio management and internal organizational change initiatives, forcing executives and managers to re-think their business models. When re-thinking the most fundamental basics of the business, difficult questions arise: How to stay focused on our primary processes? What are the core competences and processes of our organization? Manufacturing, service or both? Where do we achieve the highest ROI (Return on Investment)? In order to create organizational stability and focus, executives can use an array of strategic tools including divestment, re-structuring, strategic re-alignment and outsourcing.

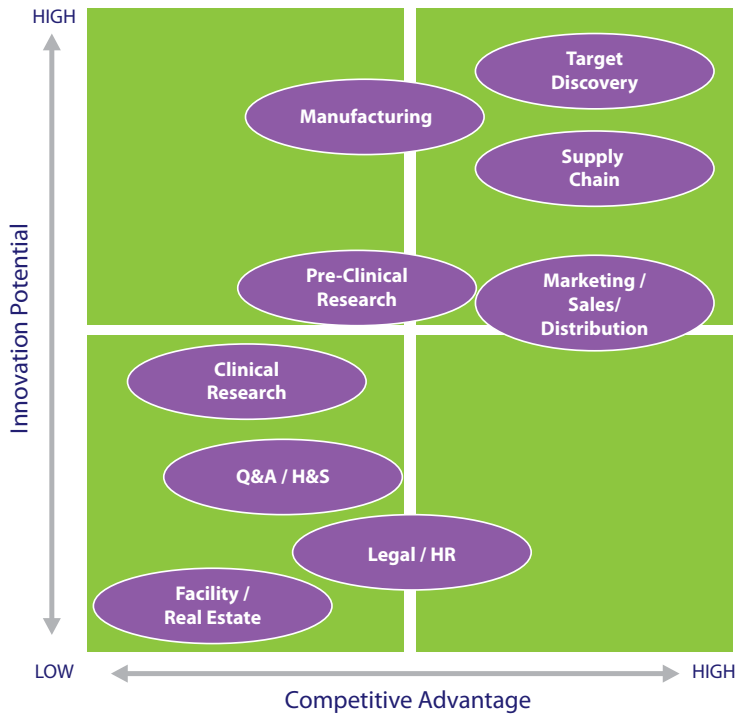


Figure 1, Innovation/ Competitive Advantage Index

Figure 1 is set up from a pharma-biotech company's perspective. It reflects the rationale why so many larger pharmaceutical companies have shifted their strategic focus to drug discovery rather than vaccine / drug testing & research. Excellent ROI rates are achieved in functional areas with high competitive and innovation capabilities. A shift towards outsourcing results in better resource allocation, less complexity and fewer core activities, which ultimately results in focus [Figure 2].

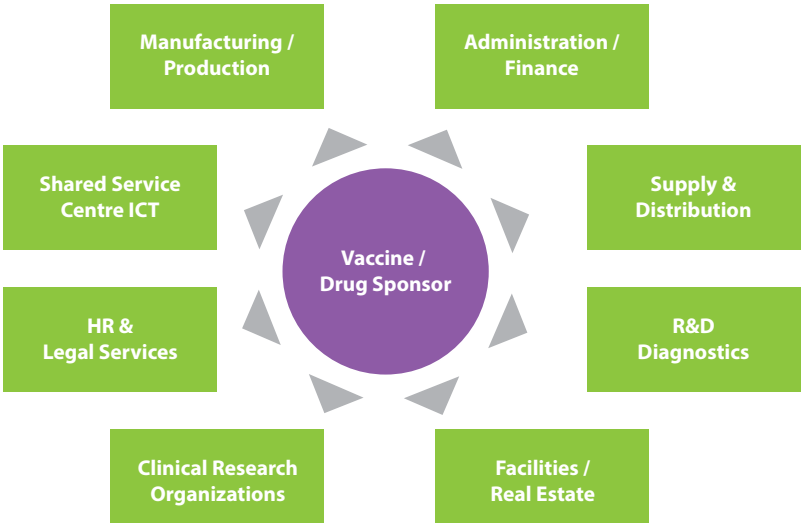


Figure 2, Strategic Outsourcing Network

When reviewing the many activities and processes related to drug and vaccine production, it is hard to pinpoint the relevant outsourcing targets. Outsourcing is usually associated with secondary support processes such as ICT, office support or facility services. Today's market place is more turbulent than ever, as reflected by the emergence of strategic networking models. Within this model, outsourcing is taken to the next level. Core competences formerly seen as primary processes are now outsourced with confidence. R&D is integrated throughout organizations and might be reviewed as a critical competence in a certain business unit and as a supportive function in another business unit. In this respect, it makes sense to review the R&D function and prioritize processes or activities that can be targeted for outsourcing. When applied to the changing drug development process, a new research & development model is required for pharmaceutical and biotech companies to stay focused on innovation [Figure 3].

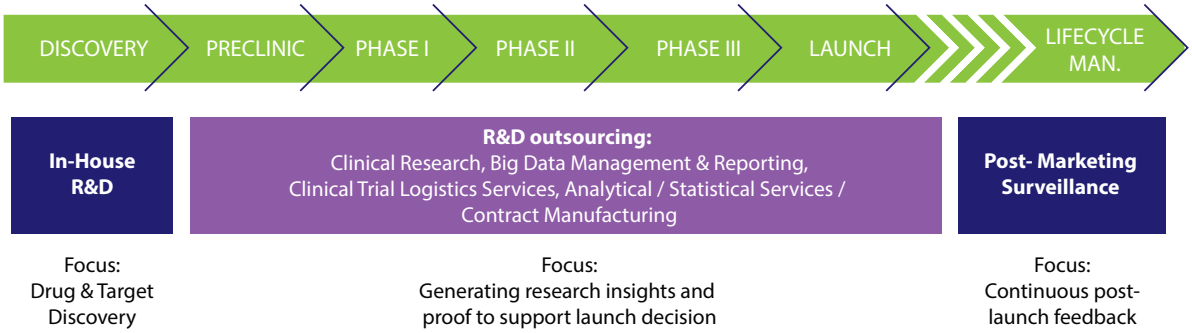


Figure 3, R&D outsourcing in relation to the development process

In a way it seems a contradiction to outsource R&D as these activities tend to be related to the area where innovation is found. However, a valuable business lesson lies in the fact that one cannot specialize in a large volume of business units and product lines. In general, pharmaceutical and biotech companies have integrated R&D in different company functions and departments. So, with outsourcing it is inevitable that certain key parts of the R&D function are included in the process as well.

3. R&D Outsourcing

It is essential to find a R&D outsourcing partner with the ability to manage strategic partnerships. But first, the following main questions need to be discussed internally: Do we want to outsource our R&D capabilities? Which R&D functions are outsourcing candidates? How do we review and assess an outsourced partnership? Which strategic partners are we considering for contracting?

A good starting point to qualify a potential partnership is to review key drivers and restraining forces, followed by a ROI-analysis.

KEY DRIVING FORCES:

- Financial metrics are influenced in a positive way. By using strategic partners, fixed operational budgets are changed into flexible contracts. As a result potential risks are reduced significantly.
- Better budget allocation on core activities. R&D has become increasingly complex and is integrated throughout the organization. By outsourcing certain parts of R&D, such as pre-clinical & clinical research, additional resources become available.
- Outsourcing supports a strategic focus. When secondary processes are outsourced, resources are more easily organized around activities that have a strategic impact.
- Operational issues are reduced significantly and efficiency is achieved. Managers and executives do not have to worry about issues such as budgeting, planning and staffing.

KEY RESTRAINING FORCES:

- There is limited controllability on operational and managerial issues of the outsourced activity.
- The Managerial function shifts from a planning & controlling focus to a networking & alignment focus. Concerning managers & executives are further away from the outsourced R&D process and will need to get used to this new way of management.
- When new outsourcing activities are initiated, a start-up budget need to be assigned.
- Risk management activity may reveal potential compliancy issues with outsourcing partners.
- From a strategic perspective, why outsourcing a function which is a potential innovation generator?

R&D outsourcing has more to do with strategy than with operations. Beyond short term quick wins and cost efficiency, R&D is oriented towards the long term. It is therefore essential to find partners in the entire supply chain who share the same long term vision.

Research[6] indicates that pharmaceutical and biotech companies increase the volume of outsourced services to CROs and CMOs (Contract Research Organizations and Contract Manufacturing Organizations). When sponsors are on the market to look into new partnerships, their number one outsourcing qualifier is service quality, followed by reliability and cost effectiveness[6]. Quality comes in many forms and therefore needs further investigation. Any sponsor who is looking into new partnerships needs to find answers to questions, such as: What is quality in relation to R&D and outsourcing? How do we assess and integrate quality with our outsourcing partners? And how can we assess and monitor quality?

Quality Level	Activities/ Qualifiers	Quality KPIs
Basic	QA/ QC: ISO15189 /GDP / GCP	Audit Results / Accreditation
Augmented	Sample Distribution & Logistics / Clinical Site Co-ordination / Data Base Management / Reporting & Analytics	Deadlines /Conversion Rates / High Sample Through Put / Turn Around Times/ Speed of Study Start-Up / Global Reach
Differentiated	Innovation Capacity / High Tech - Novel applications	Scientific Contributions / Novel Research Models / Innovative Applications

Figure 4, Hierarchy of Quality: Three Levels

Quality is explored by reviewing three layers (Figure 4) as applied to a (pre) clinical trial diagnostics function. The first layer consists of the basics that are needed when managing the diagnostics side of a clinical trial. Basic quality is built on compliancy requirements to carry out clinical trials. The next level up is augmented quality with quality indicators derived from an operational perspective. At this level a strategic outsourcing partnership is tested to its limits, especially in case of difficult and sometimes inevitable problems, such as poor logistics performance during bad weather. It is argued here that the quality of a partner lies in its ability to solve unforeseen operational problems. The third layer of quality consists of any attribute that can be defined as a differentiator.

Typical differentiators are hard to copy by other contractors and emphasize quality indicators such as the ability to innovate and scientific contributions. By dividing quality into three different levels, it becomes clear that true added value is attained through innovative and novel research applications. The conclusion here is that the establishment of a mere basic level of quality is not enough if ambitious goals are to be achieved. Innovative solutions are necessary to bring vaccine and drug development to the next level.

A VALUABLE BUSINESS LESSON LIES IN THE FACT THAT ONE CANNOT SPECIALIZE IN A LARGE VOLUME OF BUSINESS UNITS

4. Leading the way with innovation

The integration of innovation in a (pre) clinical trial setting can be a lengthy process. There are three major underlying causes:
[1] A relatively long period is necessary to carry out studies;
[2] Extra territorial knowledge institutes and legislative bodies (WHO and the FDA) publish directives[7] with compulsory and/or advisory research strategies;
[3] Innovation barriers caused by potential negative risk management outcomes. Potential outsourcing partners might stay away from being involved in new (and therefore potentially risky) research models. It might be hard to find a connotation between R&D produced innovation and ROI. Furthermore a considerable amount of time is necessary to test and validate novel research models. Contractors who are willing to go the extra mile by investing in R&D and innovation might be a better strategic choice. It seems like common sense to invest in R&D as this will stimulate innovation and secure future business. For any sponsor that wants to reach its full innovation potential, it is an absolute must that strategies are shared throughout the partner network. There is a correlation between innovation and business growth[8], which supports the rationale for investment in R&D.

THERE IS A CORRELATION BETWEEN INNOVATION AND BUSINESS GROWTH WHICH SUPPORTS THE RATIONALE FOR INVESTMENT IN R&D

Innovation is integrated in all product development stages of drugs and vaccines. In relation to R&D outsourcing, the focus should be on the core competences of the concerning outsourcing partner. Core competences emphasize the major strengths of all partners in a networking outsourcing model. The networking model enables all industry players to focus their resources on innovative activities that have a competitive advantage. This model is applicable to the outsourcing of bio-analytical services with contract research laboratories. Figure 5 zooms in on the innovative capabilities of a specialized diagnostic service company applied to vaccine testing. Light is shed on both the pre-clinical and clinical stages of laboratory testing. For contract research organizations who are specialized in bio-analytical services, innovation is derived from novel research models and the application of the latest laboratory testing techniques.

Service	Purpose	R&D Innovation
Pre-Clinical Testing / Clinical Testing	Testing of safety, immunogenicity, clinical efficacy, toxicology	Novel (Animal) Research Models, Next Gen Sequencing
Assay Development	Staying ahead by developing new analysis tools	Custom-Designed Assays, MN Virospot Assay, ELISPOT, Biospot

Figure 5, Innovation Capabilities Contract Research Laboratory

The innovative impact of novel pre-clinical research models is high. A relatively low amount of targets will make it to the final launch stage. Novel pre-clinical research methods can potentially contribute to research procedures that are much more productive and efficient. Early stage decision making on whether to proceed with the development of a vaccine will eventually yield in better ROI ratios. From a contract laboratory perspective, innovation and R&D capacity is expressed as the potential to develop new research methodologies. An example of an innovative animal model is based on a CT (Computed Tomography) scanning method[9]. A viral pilot study (Influenza pH1N1) demonstrated this technique to be suitable to generate valuable data on disease progression and severity. This research methodology can be used for the assessment of safety and efficacy of vaccination and anti-viral strategies. Since the pilot study, CT-scanning has been successfully used in relation to (Influenza) vaccine studies[10], illuminating the innovative capacity of the concerning vendor. It is not likely that a vaccine developer/ pharmaceutical company themselves would have funded such an initiative, because from their perspective, it is not core business.

More hurdles are found during the clinical trial phases of vaccine testing. During this stage it becomes considerably more costly when projects are cancelled. This puts considerable pressure on R&D functions to develop new assays and integrate the latest laboratory techniques. An interesting platform to mention here is Next Generation Phenotyping and Genotyping through 24-hour Virospot™ Assays. With these techniques, resistance monitoring is delivered significantly faster and more comprehensive, which influences the sponsor's study process in a positive way. Similar techniques are used for the custom-designed RSV Virospot™ Assay. The Virospot platform benefits from automated imaging and analysis for generating objective data. This method is 2-6 days faster compared to conventional methods and is compatible with high-throughput analysis.

Vaccine producers rely on the development of innovative methodologies in order to gain a competitive advantage. From a commercial perspective innovation has no value when it cannot be expressed in terms of ROI. The linking pin is the translation of scientific novel research into meaningful business impact. In a (pre) clinical trial setting, ROI can be expresses as reliability, accuracy, quality and speed of delivery which will have a positive impact on the process deployment of the concerning study. Sponsors should review any potential strategic partner on the basis of R&D capabilities. An objective KPI which reflects innovative capacity is the scientific track record of the concerning contractor, in terms of peer-reviewed research articles. Scientific knowledge is the source of innovation. Successful contract research laboratories have the capability of transforming science into pragmatic commercial research applications. This notion is applicable to all partners in the strategic outsourcing network.

5. Exploring new horizons
innovative vaccine testing

The annual challenge of the global health community (and more specifically the WHO), to select the most likely match between circulating viruses and vaccine viruses, is becoming increasingly more complex. This context provides the ultimate test for a contract research laboratory to proof its ability to develop innovative and pragmatic research platforms. In the example below, a contract research laboratory found an innovative solution to the continuous problem of vaccine strain matching.

PROBLEM

Recently during the 2015 influenza season, the mismatching of flu strains [A(H3N2) virus] resulted in low vaccine effectiveness. Better research insights are necessary in order to avoid similar situations. A typical vaccine production cycle consists of at least six months. Once a vaccine production line is up and running, it is nearly impossible to make adjustments in vaccine composition. To monitor vaccine efficacy and facilitate vaccine strain selection, methods are needed to characterize the antigenic properties of circulating seasonal influenza viruses. The hemagglutination inhibition (HAI) assay has been used for this purpose for decades, and is still successfully applied for subtype A(H1N1) and type B virus strains. However, the majority of recently circulating subtype A(H3N2) strains has lost the capacity to agglutinate red blood cells of various species, calling for alternative assays.

SOLUTION

The Virospot™ assay platform has been developed at Viroclinics for the detection and phenotypic characterization of influenza viruses in phase 2 and phase 3 clinical trials of new antiviral compounds. It combines classic virus culture techniques with automated sensitive detection of immunostained virus infected cells, and is now also available in a format for antigenic characterization of influenza A(H3N2) viruses. The Virospot™ MN assay has some favorable properties, including the following: It measures neutralization of virus binding to cells and subsequent infection, not inhibition of virus replication; It is relatively insensitive to differences in test dose of infectious virus between strains; Between-strain comparison is on basis of infectious units rather than replication competence; Capture and analysis of raw data is automated, with ample possibility for visual confirmation; Full traceability of neutralization and match/mismatch results to raw data (i.e., residual infection patterns); Compatible with standardized large scale testing of virus isolates. Various stakeholders in the influenza vaccine field may benefit from the advantages the Virospot™ MN assays offer, which may aid in achieving the ultimate goal of the best possible match between circulating influenza viruses and vaccine strains.

The launch of any new assay platform takes a considerable amount of time and R&D investment. The lesson learned is that contract research laboratories who frequently contribute to science through peer reviewed articles and with innovative strategies are more likely to add long term value. An outsourcing partner network can only function at its best ability when innovation is fully integrated with all strategic partners.

INNOVATIVE ASSAYS CAN SPEED UP THE VACCINE TESTING PROCESS CONSIDERABLY, WHICH SUPPORTS SWIFT MARKET DELIVERY

OUR PERFORMANCE
Within the last 2 years we processed
10,000
Genotypic Assays

OUR PERFORMANCE
Within the last 2 years we processed
100,000
Multiple Primary Virology Assays

OUR PERFORMANCE
Within the last 2 years we processed
15,000
Phenotypic Assays

6. Outsourcing Selection Criteria

Once R&D outsourcing has made it to the board room agenda, it is time to compare potential contractors. A good starting point is to plot different vendors on a partner reviewing chart [Figure 6].

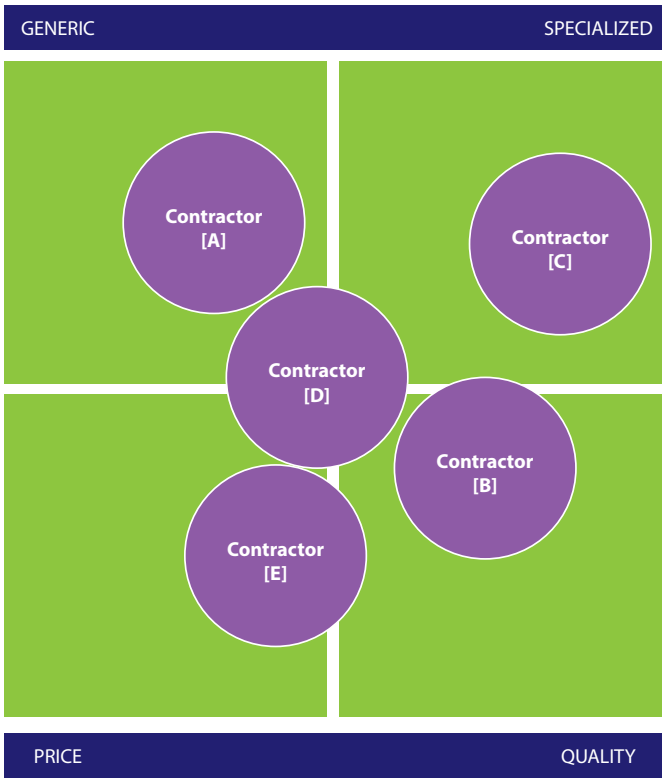


Figure 6, Strategic Outsourcing Partner Reviewing Chart

An outsourcing reviewing chart can be used to assess potential contractors on the basis of two main criteria: price /quality and generic / specialized. This model stimulates strategic review, such as the choice to contract a partner based on low cost or alternatively a strategic partnership based on quality. An interesting point to discuss is the relationship between quality and price. The strategic choice for a high quality contractor may eventually pay off. High quality/ specialized suppliers pursue a strategy based on innovation, such as novel research methods and state of the art technical facilities, which can speed up the clinical trial or R&D process. Executives and managers are confronted with a major dilemma: Are we going ahead with a low cost generic contractor (goal: short term margins) or are we going ahead with a specialized contractor (goal: long term innovation/ quality). In order to assist the decision making process a questionnaire [Figure 7] has been set up. Just like the outsourcing reviewing chart, the questionnaire needs to be filled in as a guidance tool. The eventual goal is to support the decision making process by gaining insights in strategic priorities. The decision making support questionnaire starts with a strategic review of more fundamental questions about R&D outsourcing and return on investment.

1	**Strategy**
1.1	Why are we going to outsource our R&D function(s)?
1.2	Which targets / goals are we pursuing?
1.3	What strategic choice do we need to take? Cost Efficiency or Quality?
1.4	What are the risks of outsourcing R&D?
1.5	Which R&D functions are potential outsourcing targets?
1.6	What is our history with outsourcing? What worked? What did not work?
1.7	How are we going to align and organize our company around partnerships? (internal strategy)
1.8	How are we going to establish a strategic partnership network? (external strategy)
1.9	What ROI do we want to get out of a strategic partnership model?
1.10	Thinking ahead, how are we going to manage the relationship?
1.11	Which KPIs are we going to use to assess our partnership?
2	**Selection Criteria**
2.1	What type of relationship do we want? Short Term or Long Term?
2.2	Which strategic similarities do we share?
2.3	What is the financial performance of the strategic partner?
2.4	What is the operational capacity of the potential partner?
2.5	What quality assurance and quality control track record are we looking at?
2.6	What is the global reach of the concerning partner?
2.7	How is R&D integrated in the partner organization?
2.8	What percentage of the operational budget is spent on R&D?
2.9	Which unique innovations were launched by the supplier?
2.10	What is the partner's competitive advantage?
2.11	Has the partner the capabilities to manage a strategic partnership?
2.12	Does the strategic partner has experience with working in a strategic outsourcing network?
2.13	What scientific track record has the concerning vendor established?

Figure 7, Decision Making Support Questionnaire

This metric is usually evaluated on the basis of financial performance. But return can also be expressed as knowledge, innovation capacity or efficiency, supporting the notion that there is more to outsourcing than just financial motivations. The choice for outsourcing entails a strategic shift. The internal organization has to adapt and change in line with the desired outsourcing strategy and a new way of organizational thinking. Managers will have to adjust their roles from controlling and managing to coaching and coordination and eventually let go of the concerning activities and processes. Section 2 of the questionnaire deals with operational criteria to look into, when starting a potential strategic partnership. The questions can be used for discussion purpose and will provide insights in the capabilities and operational fit between the potential outsourcing partner and the sponsor. The first question of section 2 determines the type of relationship with the concerning vendor. If the focus is short term, it is likely that cooperation is based on a basic customer-supplier relationship. In case of a mid or long term perspective, the nature of the relationship will be more strategic. It is likely that these types of business relationships will catalyze joined innovation processes. Sharing knowledge, competences and innovation in a partnership network requires a long term vision.

7. Conclusion

With R&D costs of $ 1-2 billion per newly developed vaccine, it is clear that stakes are high for sponsors looking into potential outsourcing partners. In light of turbulent market conditions, it might be tempting to contract low cost suppliers. Specialized outsourcing partners who are able to add value through high quality and innovative solutions can be found at the other end of the scale. This whitepaper reviewed outsourcing through two lenses: "a vaccine sponsor perspective" and "a contract research organization perspective". The outsourcing partner network can be seen as a multi-dimensional kaleidoscope of innovation potential. When sponsors are able to utilize the specialized innovation knowledge of their partners, they will bring vaccine development to the next level. There is a clear link between strategy, quality and innovation in relation to partner networking. It is recommended to look into outsourcing partners who are not solely focused on their own operations, but have the ability to convert their core competences into meaningful innovative solutions that can be shared within the network. From a clinical research organization's perspective, such added value lies in the development of innovative research models in both pre-clinical and clinical trial phases. Sponsors benefit from this approach as they are more focused on the initial drug / vaccine development phase and increasingly looking into partnerships with potential analytical outsourcing contractors[11]. With a market potential of approximately 600 vaccine candidates against 110 pathogens[12], both sponsors and networking partners face a prosperous future.

WHEN SPONSORS ARE ABLE TO UTILIZE THE SPECIALIZED INNOVATION KNOWLEDGE OF THEIR PARTNERS THEY WILL BRING VACCINE DEVELOPMENT TO THE NEXT LEVEL

8. About Viroclinics

Our mission is to improve human and animal health by serving the biopharmaceutical community with state-of-the-art diagnostics, custom-made models in (pre)clinical drug testing and expert advice on development of antivirals and vaccines. The main activities focus on testing samples of phase 2 and 3 clinical trials of new antivirals and vaccines, including serology, neutralization and cell mediated immunity assays, virus culture (qualitative and quantitative), PCR (qualitative and quantitative), sequencing, genotyping and phenotyping. Both BSL-2 and BSL-3 labs are available. As a separate business unit, Viroclinics Xplore offers early stage and preclinical research studies. In addition, a separate R&D department ensures novel assay development.

VACCINE TESTING PLATFORM

Viroclinics operates at a global level and is the preferred testing laboratory for several of the top 10 biopharmaceutical companies. We specialize in viral targets including Influenza, Polio, RSV, Rabies, MERS, Rhino, hMPV, Dengue, Chickungunya, VZV, and more. Our experience is based on extensive testing of VLP, live attenuated, DNA, toxoid, conjugate, inactivated and subunit vaccines. Throughout the years Viroclinics established an impressive track record by supporting studies in all phases of vaccine development, with innovative pre-clinical models and customized clinical models. A wide range of assays are available to test vaccine safety, efficacy, immune toxicology and pharma kinetics data.

THE VIROVACCINE TESTING PLATFORM OFFERS:

- Best in class molecular assays, including PCR and Next Gen Sequencing;
- Cutting edge serology assays, based on the latest ELISA methods;
- Innovative cell based assays including Immuno Spot, (ELISPOT method);
- Novel research techniques including the in-house developed Virospot™ MN Assay platform, a novel tool for antigenic characterization of influenza viruses and serology. Customized assay and protocol development is integrated which allows for standardization and validation procedures to support routine application in a clinical trial setting;
- Virus culture assays are equipped with multiple read outs to safeguard virus detection in clinical samples;
- Flow cytometry, ELISPOT and Biospot equipment are in place to assess cell-mediated immunity, antibody-dependent cell-mediated cytotoxicity, viral plaque counts, size and growth kinetics;
- High resolution viral plaque assays enable studies on inhibition of both single and multiple infection/replication cycles;
- Genotyping of virus isolates has been optimized to such a level that high quality gene sequences are obtained directly on patient materials with low viral load.

With state of the art innovative research methods and technologies, Viroclinics provides high quality data to support vaccine development. With the vaccine testing platform you are assured of faster, more efficient and innovative testing, supporting a swift market delivery.

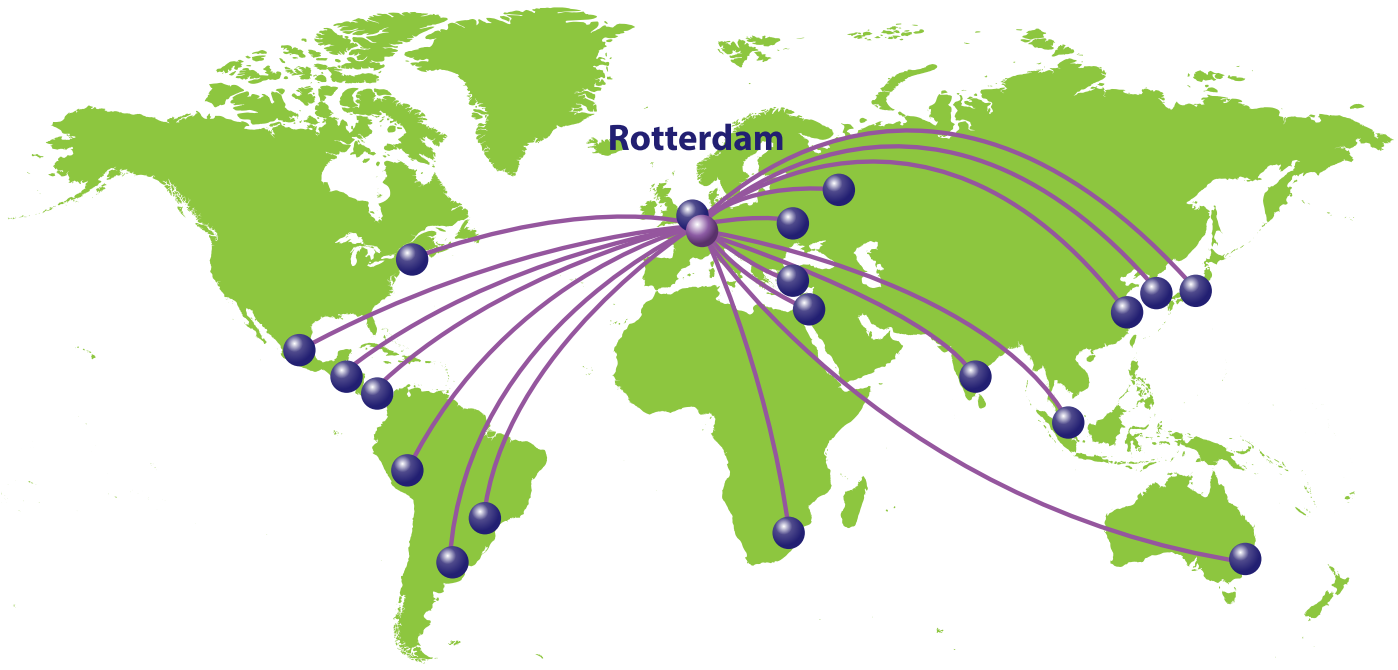
OUR VACCINE DEVELOPMENT SERVICES INCLUDE MAIN VIROLOGY TARGETS, SUCH AS INFLUENZA, POLIO AND RSV

QUALITY IS IN OUR DNA

Viroclinics has adopted a high quality standard in all operations, testing procedures and reporting. The quality management system is based on NEN-EN-ISO 15189, expanded with elements of GCP and GLP, to comply with regulatory requirements and facilitate regulatory submissions. It is accredited by the Dutch Accreditation Council which audits and visits the facilities on an annual basis. The quality standards are monitored using an internal auditing scheme and the facilities are regularly audited by customers and contract organizations. The standard operating procedures and validation reports will be made available to contracted sponsors upon request.

GLOBAL REACH

Specialized logistic activities include preparation of sampling kits, on-site sample handling instruction, courier transport, sample tracking and tracing (e.g. guaranteeing temperature controlled supply chain and online-sample timelines), and management of sample processing labs. Viroclinics supports a smooth logistical flow of samples from all over the globe, and works together with sites in USA, Mexico, Panama, Costa Rica, Peru, Brazil, Argentina, Ukraine, Russia, Turkey, Israel, South-Africa, India, China (Processing and Test Laboratory), Singapore, South-Korea, Japan and Australia.



Global Reach, with 18 processing labs

GLOBAL
OPERATIONS

INTERNATIONAL
Presence

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