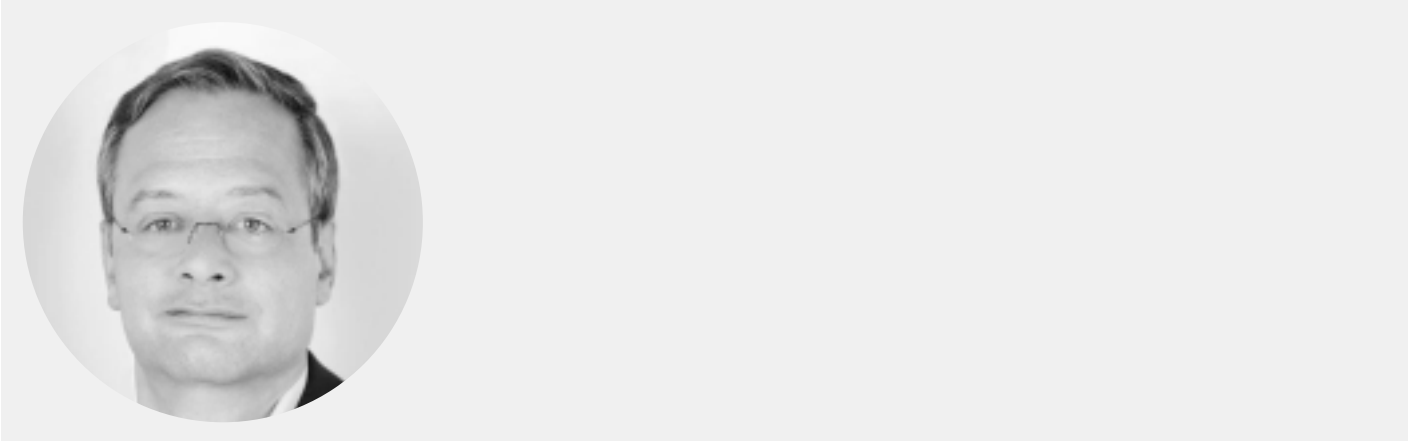
Interview: Peter Schoevers – CEO & Co-Founder, Julius Clinical, The Netherlands



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Peter Schoevers, CEO and co-founder of Julius Clinical, explains how this innovative and thriving organization allies the academic strength of an ARO with the business-oriented leadership of a CRO. Julius Clinical aims to become the partner of choice for the pharmaceutical industry by strengthening clinical trial credibility, enhancing its quality and improving cost-effectiveness.

You worked for Solvay Pharmaceuticals for 10 years at international management positions and also founded two other companies (MarviQ, an internet based application service provider, and Drug Discovery Factory, an entrepreneurial VC-like holding company). What potential did you identify when you decided to co-found Julius Clinical?

Julius Clinical was established as a spin-off from the Julius Center for Health Sciences and Primary Care at the University Medical Center (UMC) in Utrecht, which is the biggest medical center in the Netherlands. The Julius Center was founded by Rick Grobbee in 1996, after the merger of the UMC's departments of Epidemiology and Public Health with Clinical Epidemiology. Overall, the center contains an incredible wealth of expertise in the disciplines of epidemiology, public health, general practice, biostatistics, and medical technology assessment. The Julius Center also contains a clinical trials department, the Clinical Trials Services Unit, which was started mainly to operate investigator-driven research before moving towards commercial, sponsored studies for the pharmaceutical industry. Considering the increased demand for streamlined proposals, enhanced

international reach, and highly qualified staff as well as due to the increasing number of requests that the Julius Center was receiving at the time, the board of the UMC Utrecht decided to give the organization a chance to spin-off and develop its activities as a separate company.

In 2008, the University board asked me to estimate the potential of this ARO, and I straightaway identified a very promising future! It was obvious that there was a huge opportunity for a Research Organization with an academic outlook and roots that would also offer industry standard CRO operations. The increasing interest in ARO involvement from the pharmaceutical industry was the result of a number of scientific publications in prestigious medical journals that questioned the credibility of clinical trial results. These publications contained criticism on, for example, the lack of independence of investigators, the role of CROs and the fact that study design, interpretation and publication sometimes favor the sponsor company's product. Pharmaceutical companies took this criticism to heart and made important steps to improve the objectivity and inherent quality of their clinical research to increase the reliability of its outcomes. This is exactly where Julius Clinical comes in. We offer the benefits of an ARO in terms of science, protocol advice, statistics and interpretation of the data. In addition, we also take responsibility for the operations of the study or, in other words, for the crucial step of the collection of the data.

In this regard, an organization that could ally the academic strength and credibility of an ARO with the operational capabilities of a CRO would have a very promising potential. So far, we have indeed been very successful! After only eight years on the ARO-CRO market, we are the second player globally in terms of revenue in the ARO sector. We currently operate in 32 countries with a strong focus on Europe and Latin America. In addition we have experience in Asia and North America.

Considering the international scope of Julius Clinical and its Dutch roots, what attracted a company like Pfizer to choose Julius Clinical to perform the CAPiTA project (one of the largest vaccine efficacy trials ever conducted) in the Netherlands, and not in another country?

CAPiTA is to date the largest vaccine trial worldwide conducted in older adults. Its primary objective was to establish the efficacy of a 13-valent pneumococcal vaccine. For these types of trials, the Netherlands is an ideal location. First of all, a large part of the older population had never received any comparable vaccine. Furthermore, our first-line healthcare and GP network are excellent. Dutch patients don't go to the hospital without having first consulted their GP. Moreover, patients generally consult the same GP throughout their entire life. Dutch physicians thus know their patients really well. This kind of close relationship ramps up the process of finding the right participants for clinical trials and allows for an effective follow-up. Finally, the remarkable density of

the population in the Netherlands is particularly helpful to conducting such large-scale and logistically challenging clinical trials.

In the context of strong cost-containment across Western Europe and specifically in the Netherlands, demonstrating indisputable drug efficiency and long-term outcomes in clinical trial results has become absolutely necessary for pharma companies to receive expected pricing and reimbursement. How can this context highlight Julius Clinical's competitive advantage in comparison to other CROs?

Julius Clinical's unique combination of an ARO and CRO surely appeals to pharmaceutical companies. Among other reasons, pharmaceutical companies choose to partner with us because we offer cutting-edge protocol advising. Through our world-class academic network, we access experts with an excellent understanding of the requirements expected by regulators, which helps build the protocol design that will deliver the outcomes needed.. For certain clinical studies we also run cost or pricing studies in parallel to clinical trials supported by our in-house health technology assessment group. These kinds of services truly helps companies to know what they can expect in terms of reimbursement and pricing a long time before they actually reach this phase.

Furthermore, smart design of clinical trials is our specialty. It can tremendously reduce the overall costs of studies as well as strengthen the credibility of clinical outcomes. It starts by questioning whether a trial can be better performed, more efficiently and faster, while never losing sight of the reliability and high quality of our work. In order to increase the credibility of clinical outcomes, we add extra checks and balances: firstly, by giving more responsibility to independent academic researchers; secondly and maybe most importantly, by maintaining the freedom to ultimately publish clinical trial results without restrictions – even if findings may not favor the new treatment. Publishing study results is indeed characteristic for academic research and essential for our academic credibility.

Most sponsor company representatives agree that there are advantages to working with an ARO. However, it also became apparent to me in the early days of Julius Clinical that we should not be "academic" in our operations. In order to be successful we have to offer services that can compete with any global CRO. It is why we have invested heavily in compliance management, training, and quality assurance and we have hired experienced staff from pharma companies and CROs.

CROs have in the last decades evolved from being a provider of non-core services to being an integral part of the drug discovery and development process. What are your main assets that differentiate you from other CROs when you are partnering with pharmaceutical companies?

So far, we have focused on phase III clinical trials and on very large studies for FDA and EMA approvals, building on our background in epidemiology. We like complexity; either caused by the size of the studies, its planning, its logistics or from extremely innovative compounds. We obviously prefer being involved at a very early stage of the planning process, when the pharmaceutical company is still designing the study and drafting its protocol, in order to really make the most of our key features which truly differentiate us from other CROs.

Julius Clinical offers its partners a very unique combination of the latest academic insights and expertise. Pharmaceutical companies may argue that they already hold this academic expertise within their organization, thanks to opinion leaders participating in their scientific steering committees. These advisors, understandably, are often not aware or do not prioritize the operational and cost implications of their considerations. This leaves the sponsor in a tough position liaising between scientific advisory boards and the CRO. Julius Clinical has fully integrated this academic expertise in its CRO activities. Our academics, operational team and business development managers collaborate closely to ensure that the scientific, operational, financial and economic aspects of the study are perfectly aligned.

Secondly, we can rely on a strong and extremely committed network of academics and physicians all around the world. This starts with our network of Key Opinion Leaders (KOL) in various therapeutic areas. For example, Rick Grobbee, co-founder and Chief Scientific Officer of Julius Clinical, is an international KOL in clinical trials and epidemiology with a special focus on cardiovascular and metabolic studies. The close network of KOLs and associated scientists allows us to communicate with clinicians as peers, rather than simply as service providers. If issues arise at a given site, the problems can be directly discussed and often resolved between the scientific staff of Julius Clinical and the academics and clinicians in the field. These short and easy communication lines positively influence patient recruitment, patient retention and other vital aspects of the study, thanks to the leadership of local KOLs collaborating with us. The peer-to-peer management model indeed allows our organization to foster partnerships with key medical centers, academic leaders, and investigators, and above all to ensure commitment and adherence to study guidelines of local doctors all around the world.

The peer-to-peer management model also nicely illustrates Julius Clinical's open and involved atmosphere with very short and direct communication lines. We coordinate clinical studies from a central office in Utrecht, the Netherlands, in collaboration with a large international network of local partners and academic centers around the globe. Other CROs have adopted a completely dispersed geographical model. However, we are free to choose in which countries we want to conduct our studies by only considering our clients' interests, and not because we already have an affiliate in any specific country.

In addition to this expert background, Julius Clinical also has a very specific business model, based on fixed prices. Why have you chosen to differ from your competitors in this matter?

It is very interesting to see how outsourcing is organized in the pharma industry compared to other industries. Surprisingly, the current practice is to focus on input and cost instead of output and results. In some cases this can lead to business practices focused on the CRO with the lowest bid, regardless of the feasibility and offered scope of the research. In my opinion, this pricing system is the main driver of the increasing costs of clinical research and of the lack of innovation.

As a relatively new player in the industry, it was a logical choice for Julius Clinical to prepare for the needs of sponsors in the near future by focusing on efficiency through investment in technology and IT and by introducing output-based instead of input-based pricing. Julius Clinical prefers to contract a clinical study based on a fixed price model. The incentives built in the fixed price model guarantee that the sponsor and Julius Clinical share the same objectives and focus together on relevant study outcomes at a reasonable cost.

One example of the pertinence of our pricing model concerns the CRO budget, which is often calculated based on the (average) number of monitoring visits per site. The sponsor thus has an interest in having fewer sites with more patients per site, while the CRO's profitability increases with more sites and fewer patients per site. Nevertheless, with our fixed price per patient model, the two parties share the same interest, and out-of-scope discussions are rare or non-existent, which saves a lot of time and energy.

All in all, the risks and responsibilities for completing a study on time are shared. The fixed price model guarantees that we are 100% focused on efficiency and on the outcomes of our studies, instead of focusing on the extra-fees that we could be charged for out-of- scope services. If this fixed price model would be broadly adopted by the industry, I believe that the technology investment and change in business approach would decrease clinical research costs by as much as

50%, while maintaining the same level of scientific and operational control.

What is your vision for Julius Clinical for the next five years?

We will continue to build a global leadership position in our niche. As we value our relationships within national and international networks, our goal for the upcoming years is to further expand this network of academic centers and partners, while we will strive to continue our revenue growth, by expanding our study portfolio. We however want to remain distinctive in our approach: intelligently organizing relevant clinical studies whilst completing clinical studies on time, on budget and with indisputable quality.

A very important emerging trend in the CRO industry concerns strategic partnerships of CROs with big pharmaceutical companies. These strategic partnerships are representing an increasing part of the business activities. Market reports estimate the proportion of phase III studies that are contracted through these partnerships at 75%. Even though we see that pharmaceutical companies are increasingly allowing other contractors beside the preferred partners, this trend has important implications for Julius Clinical. We are currently exploring opportunities for alliances with other AROs and with CROs in order to better position ourselves in this market.

In terms of therapeutic areas, our core focus has historically been on cardiovascular diseases, diabetes and infectious diseases. We are currently strengthening our expertise in Alzheimer, ALS and oncology, and may decide to extend our experience to other therapeutic areas.

We have been fortunate to work with the majority of the global top 10 pharma companies. We also focus on the growing segment of the smaller biotechnology companies. Those companies tend to outsource the vast majority of their development work as they often have limited resources. Consequently their outsourcing partner must be able to offer a full service agreement, from protocol writing to statistics and study report. Biotech companies are price-sensitive, and at the same time very conscious that the design and execution of their studies must be excellent. These rationales, and the fact that they are often academic spin-offs themselves, make them an interesting target for ARO efforts.

Finally, we are very proud to be able to attract key people from the CRO industry. I am personally very happy that Aize Smink, who was previously the COO of Chiltern (one of the top ten CRO companies worldwide), recently became the new COO of Julius Clinical.

In summary, as CEO of Julius, I am truly proud of the unique role played by Julius Clinical in clinical development, and we are excited about the future opportunities to foster innovation, cost

effectiveness and true collaboration with the industry.

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