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Clinical trials address a triple bottom line: increasing health, increasing knowledge, and increasing business

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Trial Nation is a non-profit public-private partnership organisation consisting of all five Danish regions, the Ministry of Industry, Business and Financial Affairs, the Ministry of Health, the umbrella organisations for patient organisations and physicians respectively, and several life science companies dedicated to running clinical trials in Denmark. CEO Marianne Pilgaard outlines Trial Nation's purpose and key milestones, Denmark's fundamentals as a clinical research destination, and where she hopes to take the organisation over the next five years.

What is the purpose of Trial Nation?

Our purpose is clear: to increase the number of clinical trials in Denmark. There is fierce international competition and Denmark is doing very well due to our longstanding system-wide focus on becoming the best. This focus spans from the level of ministers, across relevant authorities, the strategic and administrative levels of all Danish hospitals to patient organisations and medical societies. Trial Nation has a fantastic foundation for its purpose.

Clinical trials address a triple bottom line: increasing health, increasing knowledge, and increasing business. I'll expand that view, but first a bit of context.

The Danish government launched a life science strategy in 2018 which combined two initiatives to form Trial Nation. The first was to connect pharmaceutical companies with the relevant researchers and the second was to attract early development Phase I and II trials to the country.

Our mission is to increase the number of clinical trials in Denmark, both in pharmaceuticals and in MedTech. Trial Nation works to bridge the right partners, find suitable access to clinical environments, facilitate work in clinical environments, framework conditions for clinical trials, and provide knowledge about clinical trials and Denmark as a destination for these trials.

This allows us to pursue the triple bottom line I previously described. The patient participating in a clinical trial can access development-stage treatments. The clinical environments for clinical trials are upgraded both with regards to methodology and with the possibility to provide options for patients to receive more hands-on treatment which provides value for both the healthcare environments and the individual physicians working on the clinical trials. Moreover, attracting these clinical trials improves investment and benefits the long-term health of a country's population.

What are the key milestones achieved over the last two years?

Denmark has maintained its ability to run clinical trials in non-COVID indications during the pandemic and has also attracted several trials related to COVID. Trial Nation led a strategic fortification of COVID related clinical trial capacity in order to handle the surge of innovation for coping with the acute challenge that the pandemic brought, all of which needed clinical validation. Our clinical centres for both infectious and respiratory disease have been instrumental in maintaining research capacity while managing the disease without case numbers exploding.

Another milestone is that for the first time, globally we believe, we will be able to let patients and healthcare providers answer a simple but pivotal question: "Is there a clinical study for me?" We are developing what we believe is a global first: a real-time updated overview of clinical trials. There are several innovations built into this tool. It will draw data from our national authorities, thereby being a catch-all tool for pharmaceutical, MedTech, and procedural clinical trials. Secondly, and also very important, it will display actively recruiting sites. The milestone here is that we have acquired funding for this unique infrastructure that will benefit the entire Danish clinical trials ecosystem. 2022 will be the go-live year. First, we roll out pharma trials from selected disease areas and across the next quarters, MedTech and procedural studies will be added in parallel with all disease areas. This creates greater access to clinical trials for a larger number of patients and allows physicians to find suitable trials for their patients.

The digitalisation of health is a mega trend that requires mega solutions. Denmark is not only at the digital forefront, but we have some of the most complete and longstanding health registries

around. We have been able to both drive and assist Danish stakeholders in putting Denmark on the global map regarding the next big step for clinical trials – decentralisation: The Danish Medicines Agency published the first-ever guideline on using decentralised elements in clinical trials– it is now moving towards version 3.0 in a multi stakeholder-driven process that include perspectives from patients, clinicians, and industry. Trial Nation is part of a project on decentralised clinical trials funded by the Innovation Fund Denmark which provides opportunities in strengthening the area of clinical trials with decentralised elements.

Why do companies choose Denmark as a research investment destination?

The first reason is data quality. There are many reasons for choosing Denmark as a preferred country for clinical trials, but I am placing data quality front and centre. The regulatory decisions that are required for a medical innovation to reach the patients are made based on data – and the quality of that data is paramount for companies as well as regulators.

The second is clinical access. Through the proven feasibility services that Trial Nation provides via our integrated position with the national hospital owners – the five Danish Regions – we can provide a coordinated national response to feasibilities.

The third important factor is relationships. Trial Nation promotes, facilitates, and maintains longstanding relationships between clinicians and commercial health innovators like pharma and MedTech companies. This is a highly important, and perhaps underrated, element of an efficient and successful clinical trial.

The fourth is openness. Danish regulators, authorities and hospital owners are extremely open to dialogue with sponsors of clinical trials. Trial Nation is routinely involved in the establishment of fruitful interactions. This openness is a cornerstone in maintaining a dynamic approach to innovating what is a tightly regulated sector.

Also, Denmark’s universal healthcare covers close to 100 percent of patients that choose the public healthcare system. Our experienced clinicians and clinical researchers are frontrunners in research with specific skillsets for clinical trials. Additionally, there is a high level of trust with patients that understand that participation in the clinical trial is in their best interest.

For example, in oncology – the clinical specialty with the greatest volume of clinical trials both in Denmark and globally – Denmark is positively positioned regarding technology as a result of early research into tumour characterisation. Therefore, skills related to whole genome sequencing are

well established as well as infrastructure such as the national genome centre which gathers data and uses the extensive public-private collaborations. Moreover, the national health system safely gathers the health data of all Danish citizens which can be accessed by clinical trial practitioners with permission.

No clinical trial is approved without a sound scientific hypothesis that needs to be tested and a sound ethical approach. Clinical trials are highly regulated which is a safeguard in itself and it is the clinical community that receives the feasibility requests for the planned patient population and determines whether it would be beneficial for the patient, if there is a sufficient amount of patients who could participate in the trial, and whether it is the right fit to Danish treatment practices.

Through the eyes of sponsors, clinical trials can be seen as a betting game with a huge business cost. Perhaps it is more of a rhetorical question, but how do you balance investment and science?

Trial Nation is not the right organisation for a purely commercial liaison. We do however support companies that are established in Denmark and wish to attract clinical trials to the country. Our aim is to showcase Danish clinical trial capabilities by maintaining a dialogue between stakeholders, presenting the data, and speaking on specific development pipelines together with our clinical experts with the purpose of finding a suitable match to conduct the clinical trials.

What is Trial Nation’s strategy to maintain or strengthen Denmark’s position on clinical trials within the EU?

Trial Nation has a focused scope which is to increase the number of clinical trials in Denmark in pharmaceuticals and MedTech. Due to the level of competition between countries for conducting clinical trials that improve their populations’ health, Denmark maintains its position through continuously improving its offering. This is accomplished through facilitating better collaboration between the relevant life science company, environment, patients, and qualified professionals. Another important component is to remain ahead of next-generation clinical trials, being in the forefront of emerging trends.

How do you address regional competition?

We believe in building on our strengths. Denmark is fortunate to have an established presence of clinical trials in our country and therefore has a modus operandi in attracting clinical trials.

Close coordination and private-public partnerships are a stronghold for Trial Nation and Denmark, ensuring well-functioning clinical trials are a key aspect in attracting collaborations to uncover medical solutions into the future. Also, being at the forefront and being part of the development of the emerging trends that shape the future is essential.

We believe that we are able to compete in this regard.

What are some specific projects you are particularly proud of for Trial Nation?

I would like to draw attention not to specific projects, but to two examples selected from some of the excellent clinical environments where the solutions of the future come to life. The list could have been so much longer, and I struggle to limit myself to two. My first example is a Phase I unit based in Copenhagen which acts as a hub for paediatric oncology and also sees patients from other Nordic countries. My second example is related to how effective networks can help solve societal challenges, and it relates to a large scale Danish follow-up on the implementation of COVID-19 vaccines. This is where investigators who have developed a close collaboration under the realms of Trial Nation have managed to launch and carry out a national follow up of all COVID-19 vaccines rolled out in Denmark – an extremely complex feat to answer urgent and relevant questions. This is a showcase example of what clinical trials can bring to society.

Where do you see Trial Nation as an organisation in the next three to five years?

Trial Nation will build on its digitalisation agenda that it is currently only beginning. Denmark already leads the EU commission DESI-index (Digital Economy and Society Index) for 2021 and, with the digitalisation goals of the Danish public healthcare sector, there is an excellent basis for the digitalisation of clinical trials.

We have taken the first steps in implementing decentralised elements in clinical trials. Our regulatory authorities strongly support this agenda and are seen as a spearhead internationally. One example is the guideline on decentralised clinical trials which was first published in May 2021 and is continually updated based on input from close public-private partnership loops, another Danish forte. Trial Nation is one part of this loop.

In addition, we help drive the digitalisation of clinical trials in several other ways. For instance, we develop digital tools that will enable patients and physicians to get access to clinical trials which may be relevant to them. This is unique in the sense that having access to up-to-date real-time information on possibilities to participate has not been seen before and is a way to create better and more equal access to possible clinical trial participation.

Furthermore, there is a shift regarding the evidence required for certain classes of medical devices and MedTech solutions. New regulations require a higher level of clinical documentation for both existing and coming solutions and the need will escalate over the coming years. Here Trial Nation will assist in establishing excellent readiness in the environments relevant to produce the evidence needed. Denmark has the potential to be the go-to country for generating the evidence needed, building on our strong tradition for clinical research and the high level of digitalisation and at Trial Nation we facilitate unleashing and showcasing this potential.

Another area where Denmark is a very relevant collaboration partner is the trend by which traditional data generation from clinical trials is augmented with additional data, for instance from registries of a different kind. This trend is early in development, and we work to facilitate the shaping of this interesting field.

Trial Nation is an association that is small in numbers, but which has a central impact on clinical trials in Denmark, and we will continue to be at the forefront over the coming years. We see great interest from many countries in how this model works, and we have tailored a model with a unique fit to our context.

What learnings did you bring from your past experience in the private sector to your current leadership role?

As a result of my background in different roles in the pharmaceutical industry, the clinical trial process and company language was familiar to me. I have seen patients gain health and knowledge from trial participation in my previous role. It is fantastic how aligned that perspective is with the Trial Nation model. In the past two years, the workings of the public system and its complexities have provided a steep learning curve. The range of capabilities in the public system has impressed me and one of the key learnings is working in a country with a high standard of functioning public-private collaborations and a willingness to work together to find solutions.

Do you have any final comments for PharmaBoardroom's international audience?

It is important to reflect on the overall purpose of creating the solutions for tomorrow. We can create better health for individuals and the society. In this, we are all patients at some point in our life. And without patients, there are no clinical trials. Therefore, the patient perspective, transparency and understanding of patient needs are crucial to maintain trust and remain at the forefront for clinical trials.

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