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DYNAMIC AND PROACTIVE CRO FOR CLINICAL AND REGULATORY DEVELOPMENT

Enrico Perfler, CEO

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PHARMA AND LIFE SCIENCE OUTSOURCING
CONSULTING/SERVICE COMPANIES IN EUROPE - 2020

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DYNAMIC AND PROACTIVE CRO FOR CLINICAL AND REGULATORY DEVELOPMENT

Back in 2002, when the SARS virus surfaced and made its fateful leap from bats to civet cats to humans, global health experts warned that the outbreak was a harbinger of things to come. And although SARS was quickly contained, it started the chronicle of future outbreaks—swine flu and then Ebola.

Here we are again, and this time the outbreak has a 'novel' name, COVID-19, tattering social lives, crippling economies and changing life as we know it. In recent weeks, the epicentre of the pandemic has moved from China and East Asia to Italy and other European regions, which has lead WHO to declare Europe as the new 'epicentre of the pandemic'. As expected, the response has been derailing in many aspects. As healthcare systems are quickly running out of personal protective equipment and ventilators, medical device manufacturers along with the European Union (EU) have had to increase their efforts to supply all the member states with the devices vital to dealing with this crisis.

However, this was not the only factor perturbing medical device manufacturers: they also had to focus on complying with the Medical Devices Regulation 2017/745 (MDR) by 26 May 2020. With all resources focused on dealing with the pandemic, it became difficult for manufacturers and Notified Bodies to handle both situations. And thus, on 25 March 2020, the European Commission announced that it intended to postpone the MDR application date by one year from May 2020 to May 2021. This

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decision at least relieves the pressure on national authorities, Notified Bodies, manufacturers, and other actors, as it allows them to focus on fighting the COVID-19 pandemic.

"The current priority for manufactures is to contribute to the fight against COVID-19 by providing devices and services that can help patients and healthcare services, while continuing to ensure the health of their employees during this period. The decision to delay the implementation of the MDR allows manufactures to focus their resources on implementing these measures to combat the health emergency," says Enrico Perfler, the CEO of 1MED. "At 1MED we have also adopted measures to protect our employees, such as smart working, and thanks to the tools we have at our disposal we have been able to continue to support the regulatory and clinical development needs of our clients as normal."

Delivering Future-Proof Services

In the present context, where the medical device and pharmaceutical industry is struggling with the pandemic situation, 1MED is developing IT tools to capture clinical data and manage clinical sites remotely. Their clients are thus enabled to prepare or update their regulatory documentation and technical files, and regulatory authorities can audit remotely, at the same time. "We are all used to using tools to work remotely, and we have also developed a validated platflom that can be used to maintain compliance. This platform satisfies regulatory, GCP, ISO standard and privacy requirements and can be made available to our clients as part of our services. Operating as an innovative CRO we continue to develop our competences to enable us to provide up to date regulatory intelligence and services." "In addition to our IT tools to support regulatory compliance, we are developing core-competences that will make us a front-runner for assisting our clients in developing next-gen products such as wearable devices and telemedicine", states Perfler.

What leads 1MED to deliver future-proof services is its competent and experienced team who have been instrumental in laying the groundwork for the company to provide medical device development, preclinical testing, clinical trial management, and drug-device combination. The company's team works side-by-side with clients to prepare and submit reviewer-friendly technical documentation and provide tailored assistance in the negotiation with notified bodies and regulatory and competent authorities in Europe. Perfler informs, "We are in an excellent position to support our clients in reaching their goals, delivering tailor-made solutions to fit timing and budget needs, and, at the same time, ensuring regulatory compliance." To support the medical device and pharmaceutical industry, 1MED is continuously developing tools that allow manufacturers to satisfy the requirements of the MDR efficiently and allow smart working and remote monitoring of clinical sites. Examples include tools for e-TF and eTMF and they are currently finishing the development of a platform for the management of PMCF studies to collect real-world data.

Covering a Product's Entire Lifecycle

1MED follows a client-centric business approach to provide high-quality, customized and scalable CRO solutions for regulatory compliance from product concept stage, through clinical investigation, initial product certification and post-market phases, fitting both regulatory requirements and clients'

needs. 1MED specialises in medical device clinical trials and thanks to the organization's connections in the industry, they can identify the best fit for clients' needs, identify suitable study sites and assess study feasibility and probability of success.

In addition to CRO clinical services, 1MED provides support in defining the proper preclinical pathway. "We can provide support for preclinical testing assessing your medical device's safety and performance thanks to our strategic partnership with 1LAB," says Perfler. A preclinical laboratory specialized in in-vitro testing, 1LAB can develop ad-hoc experimental protocols for medical devices, matching specific technology needs. It is also specialized in advanced preclinical testing, using biomaterial scaffolding and tissue engineering technology to replicate human vessels, skin, and mucosa thus limiting the use of animal models while saving time and costs during product development.

Furthermore, 1MED supports clients with the creation of ISO 13485 compliant Quality Management Systems and/or ensuring its maintenance. "The MDR has raised the bar of the Notified Body's expectations of your technical dossier and QMS documents: the design, product verification and validation records, product labelling, risk management file, clinical evaluation file are all connected. In other words, all documentation and records of your QMS and products need to be a seamless system of data and information, and 1MED supports you in making this requirement a reality in your company," says Perfler.

Quality and Reliability

1MED strongly believes that quality is its backbone and one of its vital distinctive features. "We leave nothing to chance, and that's why our work is often complimented by our clients and by Notified Bodies," mentions Perfler, and this is the reason why they have doubled their revenue for three years in a row. To further confirm the quality of the services that 1MED provides, he indicates that the organization is an ISO 13485:2016 certified Company by TÜV Rheinland Italia. 1MED not only offers a broad range of internal competences but also collaborates with a preferred partner network and consolidated relationships. This includes European Notified Bodies, Competent Authorities, research hospitals, and clinical institutes. "We have the competences, reliability and network of big CROs while maintaining the accessibility, responsiveness and costs of a small-medium company" Perfler says.

Boasting a multi-disciplinary team with expertise in design, engineering, and certification of medical devices, combination products (drug-device), and in vitro diagnostics, 1MED's integrated solutions have been proved useful for well-regarded MedTech and pharmaceutical companies.

For the future, the company believes that telemedicine will hold the key for companies to operate seamlessly. Perfler states that "smart caring" will be crucial for at least two significant reasons. Firstly, it will help in monitoring and managing patients remotely such that they can be treated at home, thus reducing costs, discomfort and time spent for travel, and leave hospitals free for emergencies or critical treatments. Secondly, the clinical data collected by the telemedicine devices can be leveraged to collect real-world evidence which will help not only for complying to PMCF regulatory requirements but also in developing new medical procedures and tools. "1MED will be at the forefront to evolve with the new normal as we always have and help manufacturers in bringing innovative solutions from bench to bed for patient benefit, while maintaining quality and regulatory compliance," concludes Perfler.