

## Case study

# Promeditec drives growth with the cloud.



Right from the start, AppClinical Trial has been hosted in the Verizon Virtual Private Cloud at our data center in Amsterdam. The facility combines high availability and on-demand scalability with the tight security and support for regulatory compliance that are required in the clinical trial environment.

Clinical trials consume over half the \$130 billion the global pharmaceuticals industry invests in research and development each year. Italian startup Promeditec was founded to develop IT solutions that accelerate clinical trials, to help reduce the time (typically 10 to 15 years) and cost (around \$3 billion) of bringing a new treatment to market. Promeditec's AppClinical Trial solution, hosted in Verizon Virtual Private Cloud, enables a more efficient, collaborative clinical-trial process by providing a secure, reliable and scalable platform for setting up trials and capturing and managing trial data.

### **Objective: to cut the cost and time of clinical trials**

Luca Emili has great ambitions for Promeditec, the company he founded to integrate the expertise and experience of specialists in IT, security, business information management and clinical research. Promeditec's aim is to transform the clinical trials of new drugs, medical devices and other treatments through the use of innovative technology that increases efficiency, optimizes processes and helps cut the cost of bringing new treatments to market.

Promeditec's particular focus is on the first stage of a clinical trial, during which researchers

carry out initial tests with a group of participants to evaluate the treatment's safety, determine the safe dosage range and identify side effects. The \$3 billion it costs to bring a new treatment to market includes the cost of failures. The sooner the trial of a failing treatment can be halted, the less money is wasted. Accelerating this initial phase is therefore key to increasing clinical trial efficiency, taking care of patient therapies and making the best use of financial and human resources.

### **Simplified collaboration with a secure platform**

Promeditec's core application, AppClinical Trial, is a scalable software-as-a-service (SaaS) offering that provides an online environment for setting up and managing clinical trials from phase I to phase IV. It supports case report forms, document and image management, and virtual monitoring visits in clinical trials.

"Every day that can be saved in a clinical trial enables revenue generated by the sales of the developed drug to be realized sooner," says Emili. "Our solution provides a secure, stable and compliant platform that accelerates data capture and enhances collaboration between the sponsors, hospitals, laboratories and others involved in a clinical trial."

**"Verizon understands the pharmaceuticals and medical device industry and the regulations that apply to it. The Verizon Virtual Private Cloud is supported by a team of governance, risk and compliance specialists to help address business standards and compliance requirements."**

Luca Emili, Founder and CEO, Promeditec

### **Meeting complex compliance requirements**

Clinical trials are ruled by Good Clinical Practice (ICH GCP), an international quality standard, and by regional regulations such as those laid down by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA). These standards and regulations are designed to protect the safety of trial participants and assure the integrity of the clinical trial data. Promeditec's applications must be compliant to be used in clinical trials.

"Unlike many public cloud providers, Verizon understands the pharmaceuticals and medical devices industry and the regulations that apply to it. The Virtual Private Cloud is supported by a team of governance, risk and compliance specialists to help address business standards and compliance requirements," says Emili.

A key element of Promeditec's compliance is obtaining computer system validation (CSV) of the data center environment that hosts AppClinical Trial. The CSV process establishes documented evidence that the hosting environment is fit for the purpose and correctly operated to reduce risk. "Not only does Verizon meet the CSV requirement, it simplifies the CSV auditing process with a web interface that makes it easy for an auditor to identify the systems and virtual machines being used, and to the standard operating procedures, proper training, policies and document/record control," says Emili.

**"The Verizon brand is known and trusted around the world; partnering with them adds value to the Promeditec proposal as we expand our business globally."**

Luca Emili, Founder and CEO,  
Promeditec

In addition to industry-specific regulations, Promeditec must also follow regional data protection laws that mandate where sensitive data can be stored. For example, data relating to European trials must stay in Europe, and U.S. data must stay in the U.S. "With many cloud services, you have no way of knowing the geographical location of your data. In contrast, with Verizon Virtual Private Cloud, we know exactly where it is at all times, which helps us meet regional data residency requirements," explains Emili.

#### **A partnership for global expansion**

Although Promeditec is based in Italy, there are no limits to its international ambitions. Emili is counting on

Verizon's global presence, coupled with its Good x Practices (GxP) services, to support the company wherever clinical trials take it. "Being able to tap into Verizon's network of data centers will help us take advantage of opportunities for our applications throughout Europe and the U.S.," says Emili. "What's more, the Verizon brand is known and trusted around the world; partnering with them adds value to the Promeditec proposal as we look to expand our business globally."

As well as extending its geographic reach, Promeditec continues to expand its application portfolio. Recent developments include an application that lets trial participants give their informed consent electronically, and another for in-silico clinical trials, which involve performing simulation testing using IT tools to further accelerate the early stages of clinical trials.

"We don't have to worry about whether the infrastructure supporting our applications can scale to meet our needs, and we don't have to invest capital in new facilities or servers. With the Verizon Virtual Private Cloud, extra capacity can be made available whenever we or our customers need it," says Emili.

#### **Enterprise-class support for a startup that's going places**

Partnering with Verizon and using Verizon Virtual Private Cloud gives Promeditec the high levels of availability and security it needs to efficiently deliver its clinical trial application. The company can also rest easy knowing it has a data center environment that supports its compliance with relevant standards and regulations. It's a combination that allows the company to focus on future goals with confidence, while driving business performance today.

"Although we're a young startup company, we can rely on Verizon service and support structures

that meet the needs of much larger enterprises. That's a huge advantage for a company like ours, operating in the sensitive, demanding pharmaceuticals market," says Emili. "We also benefit from Verizon's worldwide presence and global brand awareness, which will support us no matter how fast or how far we grow."

#### **About Promeditec**

Promeditec delivers e-clinical solutions that support clinical trials with efficient, innovative technologies aimed at simplifying the implementation and use of IT in the clinical research environment. Promeditec works with pharmaceutical and medical device companies, contract research organizations (CROs), biotech companies and medical and clinical research institutions, helping sponsors, investigators and study coordinators to improve the quality of their clinical trial research with experience and know-how consolidated through extensive collaboration. Promeditec's AppClinical Trial platform integrates a number of modules that can be selected to provide a customized solution. The Promeditec platform is FDA, EMA and GCP compliant.

#### **Learn more.**

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