Kayentis

Global provider of eCOA and patient-centric solutions

Press Release // Kayentis forges ahead on five new eCOA service projects with emerging biopharma firms in Europe and US

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Kayentis sets up incoming EBPs, major contributors in biomedical innovation, as well as its existing clients, with contingency plans to help mitigate disruptions of COVID-19 on clinical trials

Grenoble, France, April 14, 2020 – Kayentis, a global provider of eCOA (electronic Clinical Outcome Assessment) solutions for clinical trials, today announces it is forging ahead on five new eCOA service projects with Emerging BioPharma (EBP) companies. EBP is a segment of companies driving a large portion of innovation and development in the life sciences and defined as having less than $200 million in estimated annual spending on R&D. The projects Kayentis is collaborating on involve phase 2 and 3 clinical studies in therapeutic areas addressing unmet needs in oncology, inflammation and immune disorders, women's health and rare diseases.

In response to COVID-19, Kayentis has implemented a dedicated contingency plan for sites and patients, protocols and additional support to enable these EBPs, as well as its other clients, to keep trials running.

Kayentis won the EBP contracts in a competitive bid among global eCOA vendors. Due to confidentiality, the names of the five EBP clients were not disclosed.

> "EBPs are significantly influencing the clinical research landscape; they contribute to a large proportion of biomedical innovation," said Guillaume Juge, CEO at Kayentis. "In recent times, we have seen an uptick in eCOA contracts stemming from the growth in the number of clinical trials being conducted by EBPs. Kayentis is committed to supporting our EBPs to help mitigate the negative consequences of the current health crisis."

An IQVIA institute report indicated that in 2018, 68 per cent of the whole portfolio of clinical trials were conducted by EBPs. The number of molecules under development by EBPs has grown by 15 per cent over the past two years. They also originated and launched 42 per cent of the new drugs in 2018.

> "As EBPs are active in only a limited number of project developments, with limited resources, the stakes for success are extremely high," explained Estelle Haenel, medical director at Kayentis. "Kayentis' approach to collaboration is to fill infrastructure and resource gaps. Therefore, we are very highly involved in the preliminary consultation and in issuing advice; even more so now, due to the COVID-19 pandemic. The EBPs with whom we are currently engaged solicit our expertise in eCOA and require that we guide them on COVID-19 public notices, as well as support the primary endpoint of their protocols that are critical to their businesses."

As is general practice, Kayentis has provided each of its new EBP clients with a dedicated project team, scientific support and customized solutions that address the complexity of each clinical protocol. It has also provided them with a comprehensive and detailed review of the project implementation options available, in terms of set-up and devices etc., as well as a thorough description of the workflows.

Since the COVID-19 outbreak, it has been vital to monitor on a daily basis the recommendations issued by authorities and to discuss these issues with partners and industry leaders within the ePROConsortium, of which Kayentis is a member. In addition, Kayentis has implemented:

- A strict disinfection protocol for devices issued to patients and sites

- Back-up eCOA solutions to allow patients who no longer attend site visits to complete questionnaires using alternative methods, such as telephone interviews

  An adjustable plan with very short turnaround times, logistics, processes and flexible resources to enable sponsors to carry out clinical trials, while respecting country specific or reinforced lockdown instructions

  A work from home policy for Kayentis' 140 employees located in France, the UK, the US and Japan

Kayentis has conducted studies in 75 countries, using 90 languages at 12,000 sites. Its eCOA solutions have been used by more than 80,000 patients over the last 15 years.

About Kayentis

Kayentis, a global expert in electronic data capture for patients in clinical trials, helps sponsors and CROs bring simplicity, efficiency and quality to the collection of clinical trial data from both patients and sites. Kayentis has been involved in clinical development since 2003. Over the last 15 years it has specialized in electronic Clinical Outcome Assessment (eCOA) solutions. It has conducted digital data collection for over 220 clinical trials in 75 countries (12,000 sites and 80,000 patients), employing 90 different languages. The company develops a full range of services and is now enlarging its eCOA solutions portfolio to extend connection with medical devices, as well as to enhance patient engagement.
Headquartered in France, Kayentis also has operations in Boston (MA) and recently opened an office in Tokyo, Japan, where it has a growing portfolio of projects in Asia-Pacific.

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