Begin with the End in Mind: PhaseBio will Power their Rare Disease Clinical Programs with Rave EDC — Beginning with initial Phase I study

PhaseBio Pharmaceuticals is a clinical-stage biopharmaceutical company committed to developing improved biotherapeutics for the treatment of orphan diseases, with an initial focus on cardiopulmonary indications.

THE CHALLENGE

Orphan drug development presents unique challenges for any life sciences company. Defined as a rare disease or condition affecting less than 200,000 persons in the United States[1], this presents an immediate enrollment challenge due to the limited number of affected patients, compounded with at times incomplete understanding of the disease and very limited prior data available to design effective trials. Despite the smaller pools of affected patients, these drugs still require safety and efficacy regulatory approval.

As an emerging and innovative biotech company, PhaseBio has evolved in recent years with advanced pipeline growth opportunities, developing therapies with a focus on orphan-cardiopulmonary diseases. With growing clinical programs, the need for a robust eClinical platform became a priority for them; promoting better data management, and greater efficiency through all phases of their clinical studies. PhaseBio identified the need for a robust data management platform solution and outsourcing relationships that could scale up to a large, global program.

THE SOLUTION

Along with a new, fully outsourced CRO relationship, Medidata Rave EDC will further enable PhaseBio to address current and future needs as they advance and improve their therapies — providing new and improved treatments for patients suffering from these rare indications.

Debunking the misconception that Rave EDC is just for large pharma companies, PhaseBio found Medidata's Rave EDC platform to be the single solution for their first Phase I study, yet flexible enough to scale alongside their program growth. "We have a very good understanding of our entire program beginning with Phase I all the way through to Phase III, and know ahead of time that we plan to start as a single site in Phase I, and rapidly expand as a global program," said John Lee, chief medical officer at PhaseBio.

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THE PLATFORM OF CHOICE FOR CLINICAL RESEARCH

The Medidata Clinical Cloud is the cutting-edge platform that transforms the clinical trial experience for patients, sponsors, CROs, and research sites. Designed with a unified data platform, the Rave Clinical Cloud creates a single source of truth for all study-related data. Simply put, enter data once and let the platform master and populate it throughout the end-to end suite of Rave applications. Optimize operational execution, decrease the data entry and maintenance burden, and reduce the number of clinical systems across your study teams. Throw away your list of passwords, you are now on a truly unified platform.

1. Orphan Drug Act Pub L 97-414, as amended 1984

Rave EDC's flexible architecture will support the data management trial demands as PhaseBio advances from one site to multisite studies across the globe.

Driving factors that attracted PhaseBio to Rave EDC include the unified platform, a user-friendly solution, and forward looking capabilities. Having all clinical data on one platform reduces the stress of merging data sets that would otherwise require manual effort of the internal team. "Medidata Rave has the capability to scale with us, thanks to their robust data management platform, which means that we would be able to monitor multiple studies in parallel and potentially merge data sets as needed from these studies in order to support a streamlined development plan leading to approval when we arrive at that stage, " Lee noted.

In addition, PhaseBio has the distinct honor of becoming Medidata's 1,000th customer. Medidata is the first and only eClinical company to achieve this milestone.