

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 States¹, 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

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.