BioSpectrum
the business of Bi
24 years of leveraging the business of Bio
www.biospectrumindia.co

# Envigo launches PATHWAY, an optimized safety assessment solution to enable first-in-human clinical trials

11 March 2019 | News

**PATHWAY has been designed to leverage Envigoâ??s capacity, capabilities and experience in the field to optimize safety assessment programs and deliver translational biology insights to prepare customers for first-in-human clinical trials.**



Envigo, a leading provider of non-clinical contract research services and research models has announced the launch of PATHWAY – an integrated solution that optimizes non-clinical safety assessment programs to enable first-in-human clinical trials. PATHWAY is designed to manage the complexity of the entire safety assessment process on behalf of the company's pharmaceutical and biotechnology customers by integrating safety assessment study types and bioanalytical support with scientific and regulatory consulting, program design and project management.

The decision to develop the PATHWAY solution was made in order to help the customers navigate the increased scientific and regulatory complexity facing advanced therapies going through safety assessment. The intricacy of design and management of these critical non-clinical programs, and the level of interaction with regulatory bodies required, raises the risk of introducing delays and costs to development programs. PATHWAY has been designed to leverage Envigo's capacity, capabilities and experience in the field to optimize safety assessment programs and deliver translational biology insights to prepare customers for first-in-human clinical trials.

"Our deep expertise in the complex fields of biologics and advanced therapies adds particular value to our customers with drug development programs in these growing categories. On our customers' behalf, we frequently work with regulators to determine the most appropriate interpretation of regulatory guidance as it applies to a specific therapeutic," commented Lee Coney, Envigo's Chief Scientific Officer.

"PATHWAY makes full use of our beginning-to-end understanding of the safety assessment process, and optimizes the journey to first-in-human studies. Experience of designing and conducting studies in a wide range of therapeutic modalities, and in working with regulatory agencies around the world, means we are able to anticipate the needs of a program at design stage, plan studies accordingly, and manage an optimal timeline of study execution," Lee Coney added.

With harmonized facilities with AAALAC accreditation in Europe and North America, Envigo further seeks to optimize safety assessment programs by ensuring studies are carried out at centers of excellence and where capacity permits the earliest possible start date for commencing work.