Best Cancer & Women's Health Treatments Developer – UK

ValiRx PLC

ValiRx is a drug development company, which focuses on the translation of scientific innovation into clinical candidates for cancer related conditions and women's health. Its specialised business model connects science, finance, and commerce to accelerate early-stage drug development. We find out more from new CEO, Suzy Dilly.

ValiRx identifies proprietary and novel drug candidates with the potential to improve patient lives, providing the expertise and investment required for optimised development and value creation.

Having been involved in developing clinical stage drugs for a number of years, in 2020 ValiRx, under the leadership of a new CEO, Suzy Dilly, made a strategic shift and focused its resources on preclinical development in women's health and oncology. The company identified an opportunity to use its skills and expertise to translate great science from universities and related institutions into clinic-ready and partnership-ready assets for further funding and clinical development.

ValiRx offers combined expertise in science, commercialisation and funding, so-called connected innovation, to accelerate early-stage development of new drugs. The company has already identified a number of exciting new oncology assets and is undergoing a period of evaluation for each before full adoption and in-licencing. Uniquely, the academic innovator is engaged at all stages of development and encouraged to take a stake in planned subsidiary companies, which will be established for each adopted technology.

To date, ValiRx has operated as a virtual biotech company, outsourcing laboratory work to the most appropriate suppliers for each project.

"Through this experience, and the challenges of coordinating multiple sources of data with minimal analysis and interpretation, we believe there is an urgent need for a new type of pre-clinical Contract Research Organisation (CRO) that employs the latest technologies, data curation and analysis techniques, and provides expert advice on how to apply the knowledge gained into an effective clinical development programme," explains Suzy Dilly. "Such an organisation, or Translational Contract Research Organisation (tCRO), could potentially accelerate preclinical development and reduce risk in clinical trials. This would be particularly beneficial in projects with a women's health focus."

To this end, ValiRx now intends create a tCROsubsidiary, supporting its own internal pipeline and conversely using its in-house development skills to provide services to a wide range of biopharma companies seeking a fresh approach to drug development.

"We believe that by following a rigorous process of data generation, analysis and implementation, we can improve understanding and de-risk clinical trials on our drug development," Suzy elaborates. "By offering this integrated platform to the wider industry, we will benefit from greater development and evolution of our technologies; by developing our in-house pipeline, our service clients will benefit from our experience and confidence in the value of our research."

The challenge across drug development, whether in biotech or big pharma, is that the failure rate in clinical trials remains too high – and if drug candidates fail after entering clinical trials it can be a very costly exercise. Whether the drug has failed due to unexpected toxicity, or a lack of effectiveness in treating the disease, it can be sweepingly described as having failed due to a lack of prior understanding of the drug before entering that trial.

Suzy continues to tell us that many drugs fail at Phase 3 because the benefits of the drug seen in smaller Phase 2 trials do not translate to population-wide benefits in the larger Phase 3 trials. If the Phase 2 has been designed around a narrow, carefully selected patient population, this should not be a surprise, and yet still, the majority of Phase 2 clinical trials are executed predominantly in men.

"The reasons for this are straightforward," she states. "Women, particularly of women of child-bearing potential (that is most women between puberty and menopause) are deemed a risk in early-stage clinical trials, when full reproductive and genetic toxicology studies are not complete. The risk of an unexpected pregnancy while the woman is on a treatment that is not fully tested is deemed to be prohibitive."

Thus, Phase 2 clinical trials, when drug dosing is optimised, tolerability and toxicity as well as potential benefits are assessed is carried out predominantly in men. When the trial progresses to Phase 3, incorporating a broad, patient representative population, the drug fails, perhaps sometimes due to drug absorption, metabolism or inappropriate dose levels, side effects or tolerability that is seen in the 50% of the population (women) for which the drug was not previously tested.

ValiRx's solution is to better understand the biology before the first clinical trials are commenced; to apply the analysis of that understanding to ensure patient-specific effects are predicted; and to look for ways to encourage the use and participation of women in earlier stage clinical trials.

Recently, ValiRx was recognised in the Biotechnology Awards 2022 and named Best Cancer & Women's Health Treatments Developer in the UK. The firm has evolved significantly over the past couple of years, and this evolution is intended to continue.

"The next stage is to move from a period of consolidation into a period of sustained growth," Suzy comments. "By acquiring additional capabilities and facilities, ValiRx has an opportunity to envisage a future of self-sustained drug development and an integrated, revenue generating preclinical service business."

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