CASE STUDY
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d3 MEDICINE
THINKING WITHOUT BORDERS™

d3 Medicine

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A turnkey, integrated solution for drug development strategies and stewardship

d3 Medicine challenges conventional dogmatic approaches and achieves unprecedented accelerated development pathways

Transformative thinking that provides an alternative to conventional processes in drug development has the potential to save millions of dollars in clinical trials, expand indications for drugs and open up new geographic and patient markets, according to the consultancy d3 Medicine.

Headquartered in the USA with offices in Australia, the consultancy provides strategic advice and stewardship in drug development strategy, regulatory science and due diligence to global pharmaceutical and biotech companies, private equity and venture capital groups, and government agencies.

Its highly accomplished and experienced management team has strong track records in the delivery of contemporary clinical pharmacology and R&D development methodologies to address regulatory science and commercialisation challenges. The team's goal is to facilitate the cost-effective development of medicines that meet the needs of patients, regulators and investors, particularly in geographic and patient areas which have major unmet needs.

"We offer a turnkey, integrated solution for drug development strategies and stewardship. Often we see clients who have retained a number of individual consultants with expertise in various domains who advise the client separately, but don't provide the benefit of a group discussion involving the company and such consultants. The company then has to assimilate individual pieces of advice into their development plan," says d3 Medicine Chief Operating Officer and Chairman, Leigh Farrell.

"d3 Medicine's team can advise on all aspects of drug development strategy with the client and together derive a more robust plan that has been pressure-tested from multiple angles. We also incorporate contemporary thinking in regulatory science, quantitative clinical pharmacology and biosimulation, and value focused deal-making.

“d3 Medicine provides ongoing stewardship for many clients, supporting them at pivotal times during their development programs, including interactions with health authorities, during due diligence or at the deal table with potential commercial partners. d3 Medicine can provide individual expertise or leadership, fulfil a functional role such as clinical pharmacology and translational medicine, through to provision of a virtual development or due diligence team.”

Craig Rayner, d3 Medicine’s CEO, says the company’s founders, like many peers within the industry, had seen first-hand, innovative teams constrained by checkbox views on drug development.

“Many opportunities to do it faster and better may be unlocked via embracing integrated leadership in clinical pharmacology and regulatory science coupled with advances in quantitative clinical pharmacology methods.

“Complexity has seen the core functions of drug development disaggregate as people become more and more specialised, and the integration role of clinical pharmacology has been diminished in many instances. For many, drug development has been reduced to a relay race, with the baton handed from one participant to the next. We see it as a team sport where clinical pharmacology helps bring the domains of expertise together in an integrated manner with a renewed focus on regulatory science innovation. We focus on cost, time and certainty, oriented to the patient need.”

Unprecedented accelerated development pathway

In a recent case study, d3 Medicine was retained to advise a biotech company on gaining regulatory acceptance of a new accelerated pediatric development pathway.

The client needed to develop a rationale for developing an anti-infective medicine for respiratory syncytial virus (RSV) where the first labelled indication was for children. Infants represent the highest unmet medical need population for this medication. There was no precedent for regulatory acceptance of an accelerated development pathway for this pediatric indication.

“We worked with the client to develop and execute a translational medicine strategy to support switching from adults to infants at the end of Phase 1 using preclinical models, PK/PD modelling and simulation, and clinical PK and safety data from healthy adults,” says d3 Medicine Chief Scientific Officer, Patrick Smith.

“We supported the client team at face-to-face scientific review meetings with European regulators. The regulators accepted the accelerated development strategy, enabling the entry of this promising antiviral for children as the first labelled indication.

“This was unprecedented, and it demonstrated the success of our systems approach and transformative thinking.”

A key component of the program, an adaptive design adult RSV challenge model clinical trial, was the subject of a paper recently published in the New England Journal of Medicine.

The adaptive design approach enabled the team to interrogate the exposure-response relationship, real-time, and ultimately establish dosing recommendations for future development in both adults and children using population pharmacokinetics and viral kinetic modelling.

“The adult challenge study results demonstrated that innovative trial design including pharmacometric analyses between cohorts can result in significant cost and timeline savings, reducing the required sample size by maximising information content of the collected data,” Dr Smith says.

“We were able to halve the number of patients in this trial, compared to conventional approaches.”

“By thinking this way – being faster, more efficient and taking out costs – we can assist in potentially creating new markets and new opportunities to get drugs more efficiently to patients who would not otherwise receive them,” Dr Rayner says.

“Some indications aren’t pursued for drugs because the cost of running the clinical trial is not commensurate with the reward, even in mainstream markets. But we have the skills to utilize better quality science to help inform dosing in many other populations.”