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**d3 MEDICINE**  
THINKING WITHOUT BORDERS™

# 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 dogma 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 United States 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 a strong track record in delivering contemporary clinical pharmacology and R&D strategies to address regulatory science and commercialization 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 that 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. The company then has to assimilate individual pieces of advice into their development plan," said d3 Medicine COO and chairman Leigh Farrell.

"d3 Medicine's team can advise on all aspects of drug development strategy and, together with the client, 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 value-focused dealmaking.

"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, fulfill a functional role, through to provision of a virtual development or due diligence team

Craig Rayner, d3 Medicine's CEO, said the company's founders, like many peers within the industry, had seen innovative teams constrained by checkbox views on drug development.

"Complexity has seen the core functions of drug development disaggregate as people become more and more specialized, and the integration role of translational medicine and clinical pharmacology has been diminished in many instances.



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"Many opportunities to develop medicines faster and better may be unlocked via embracing integrated leadership in clinical pharmacology and regulatory science coupled with advances in pharmacometrics and biosimulation.

"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, all 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 a rationale for developing an anti-infective medicine for respiratory syncytial virus, an indication in which the highest unmet need and first labeled indication was for infants. 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, pharmacokinetic and pharmacodynamic modeling and simulation, and clinical pharmacokinetic and safety data from healthy adults," said d3 Medicine CSO Patrick Smith.

"We supported the client team at 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 labeled indication. This was unprecedented, and it demonstrated the success of our systems approach and transformative thinking," Smith said.

A key component of the program, an adaptive-design adult respiratory syncytial virus challenge model clinical trial, was recently published in *The New England Journal of Medicine*.

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

"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 maximizing the information content of the collected data," Smith said. "We were able to halve the number of patients in this trial compared to conventional approaches.

"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. By thinking this way—being faster, more efficient and taking out costs—we can assist in potentially creating new markets and new pathways to get drugs more efficiently to patients who would not otherwise receive them," Rayner said.

The company believes in global equity in access to medicines. Its stated purpose is to revolutionize the drug development paradigm to accelerate the development of medicines that can make an impact on society.

contact

Patrick Smith, CSO  
Parsippany, New Jersey, USA  
Tel: +1-973-267-4703  
Email: patrick.smith@d3medicine.com

Leigh Farrell, Chairman and COO  
Parkville, Victoria, Australia  
Tel: +61 410 411 662  
Email: leigh.farrell@d3medicine.com