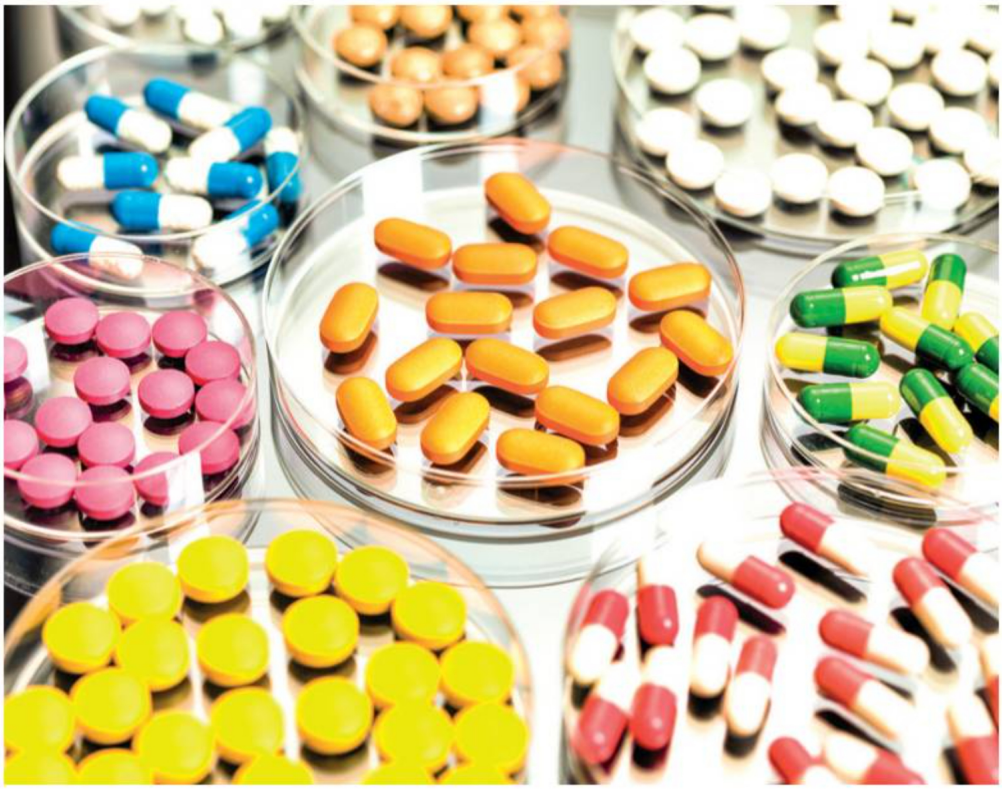
BUILDING A BETTER DOSE-FINDING STRATEGY WITH IQVIA BIOTECH



FOR DECADES, ONCOLOGY drug development has relied on the maximum tolerated dose (MTD) dose-finding method. With the United States Food and Drug Administration's (FDA's) Project Optimus initiative, the landscape of Phase I oncology trials is changing, and there is a greater focus on dose optimisation and patient-reported outcome.

A patient-centric approach to dose optimisation

Dose optimisation is a patient-centric approach that aims to identify a drug's most effective dosage and schedule, while also considering its toxicity to patients. By analysing a wider data pool of nonclinical and patient data, such as genetic make-up, biomarkers and pharmacokinetics, dose optimisation can provide a safer, personalised approach to dosing, leading to better treatment outcomes and fewer adverse events.

How does dose optimisation differ from the MTD method?

The MTD method is traditionally used to determine the highest drug dose a patient can tolerate without accounting for a range of factors affecting each patient's unique biological interaction with the drugs. Its theory is that higher doses lead to better efficacy, but this is not always true and can also lead to higher toxicity.

Dose optimisation, on the other hand, is a more targeted approach to dosing, especially relevant for novel therapies, such as targeted agents, antibody drug conjugates and immunotherapies. It also considers multivariate factors like pharmacokinetics, pharmacodynamics and biomarkers, advocating patients' comfort in treatment and efficacy.

Dose optimisation in early-phase oncology

The new dose optimisation paradigm involves a more sophisticated analysis of dose and schedule, before moving into later-phase trials. This approach will require innovative trial designs and analytical methods, such as modelling and simulation, to gather valuable insights during the early-phase oncology drug development.

An exciting shift in oncology drug development

In summary, the shift towards dose optimisation represents a significant change in oncology drug development. Sophisticated analyses of dose and schedule before moving into later-phase trials ultimately drives safer and better-tolerated treatments for patients, more efficient drug development, and a higher likelihood of success in later stages of clinical trials and regulatory interactions. Therefore, early-phase oncology studies should now include dose optimisation strategies to adhere to the new FDA guidelines.

IQVIA Biotech supports drug developers in dose optimisation

IQVIA Biotech provides adaptable clinical solutions to support drug developers in the new era of dose optimisation, and ensures effective treatment delivery to patients. Its clinical development team brings expertise from two decades of planning and executing clinical trials exclusively for biotech companies. Drawing on IQVIA's unparalleled data and advanced analytics, IQVIA Biotech creates intelligent connections to deliver powerful insights to help customers accelerate clinical development of innovative medical treatments.

For more information, visit iqviabiotech.com.

IQVIA BIOTECH

Integrated Clinical & Commercial Solutions for Biotech

We are the clinical and commercial partner you can count on for flexible solutions tailored specifically for the biotech and biopharma industry.

Our comprehensive suite of services supports you at every stage of the drug development process

- Asset Valuation & Due Diligence
- Drug Development Strategy & Analytics
- Clinical Development
- Launch Strategy & Planning
- Commercialization & Lifecycle Management

For more information, visit iqviabiotech.com