WHAT ONCOLOGY DRUG DEVELOPERS SHOULD EXPECT FROM THE FDA’S PROJECT OPTIMUS

Historically, the dosing strategy for oncology drugs has focused on the maximum tolerated dose. This paradigm has resulted in drugs’ pharmacokinetic (PK) profiles, pharmacokinetic/pharmacodynamic (PK/PD) relationships, and clinical target inhibition largely being ignored.

This paradigm is being challenged by the FDA. Project Optimus is a new guidance that aims to improve clinical trial design and results by considering safety and efficacy more fully.

WHAT IS PROJECT OPTIMUS?

These challenges spurred the FDA’s Oncology Center of Excellence to develop a new guidance called “Project Optimus” to address issues relating to dose optimization in clinical trials assessing the safety and efficacy of oncology drugs.

WHAT’S THE IMPETUS FOR PROJECT OPTIMUS?

Historically, the dosing strategy for oncology drugs has focused on the maximum tolerated dose. This paradigm has resulted in drugs’ pharmacokinetic (PK) profiles, pharmacokinetic/pharmacodynamic (PK/PD) relationships, and clinical target inhibition largely being ignored.

WHAT DO DRUG DEVELOPERS THINK WILL BE THE MAJOR IMPACT OF PROJECT OPTIMUS ON ONCOLOGY DEVELOPMENT PROGRAMS?

- Increased Timeline: 38%
- More Streamlined Development: 28%
- Increased Development Cost: 19%
- Approval Delay: 9%
- Higher Failure Rate: 6%

WHAT STEPS SHOULD YOU TAKE TO BE PREPARED FOR PROJECT OPTIMUS?

1. Perform dose-finding studies in a pre-market setting
2. Focus on improving tolerability
3. Meet with the FDA as early as Pre-IND to discuss your dosing strategy
4. Plan for interim analyses and allow for intra-patient dose escalation
5. Focus on improving tolerability

CERTARA CAN HELP YOU GET YOUR DOSE RIGHT THE FIRST TIME!

With deep experience in model-informed oncology drug development, dosing and regulatory strategy and advices, we’ve helped advance hundreds of oncology programs. Our proven, integrated approach using quantitative methods can help you to navigate this regulatory change.
Historically, the dosing strategy for oncology drugs has focused on the maximum tolerated dose.

Visit us at Certara.com/projectoptimus to learn more!
Thus, cancer patients often struggle to tolerate their medication doses long-term, requiring dose modifications including dose reductions and holidays. What’s more, for many oncology drugs, their dosing or schedules have been modified to address safety or tolerability issues after regulatory approval.

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Evaluation of additional dose levels for safety & efficacy/activity

Dose & exposure response relationships

Focus on dose intensity and adverse event time course

Focus on toxicity past the dose limiting toxicity criteria

Scrutiny of adverse events that effect patient quality of life

Integrated data analyses

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MORE STREAMLINED DEVELOPMENT 28%
INCREASED DEVELOPMENT COST 19%
APPROVAL DELAY 9%
HIGHER FAILURE RATE 6%

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*Number of respondents = 576
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