White paper

Data & Digital

Breaking through barriers with integrated trial optimization

An innovative approach to clinical study design

In the evolving landscape of clinical trials, strategic integration and scientific strategy are paramount to success. PPD Integrated Trial Optimization (ITO) Solutions are agile projects that incorporate multiple layers of data across various functions. This approach aims to integrate the functional outputs of participating teams—including, but not limited to, feasibility studies, operational strategies, medical insights and Patient First solutions—and interpret the results to develop optimized trial strategies.

Organizations must balance the requirements of regulators, sites, payers, and, most importantly, patients to ensure successful studies. This comprehensive approach ensures that the scientific strategy aligns with the expectations of all decision-makers, while also considering the needs of patients and sites involved in the study.

By doing so, sponsors can explicitly address the trade-offs inherent in study design. For example, they can evaluate how the collection of additional data might impact enrollment, retention and timelines. This enables them to make informed design decisions that optimize their objectives.

Areas of opportunity

Clinical operations

In response to a patient need for greater convenience where clinical trial participation is concerned, a comprehensive Decentralized Clinical Trial (DCT) ecosystem can be useful, enabling trials to be conducted remotely, outside of typical settings such as hospitals or research centers. This network of services, technologies and strategies can be leveraged to collate real-world data (RWD), recruit a wider pool of patients without geographical constraints and reduce on-site visits.

Clinical development

Ultimately, with increased patient enrollment and retention comes accelerated clinical development. A patient-centric approach that improves accessibility and prioritizes flexibility and communication will help maintain participation, even with changes in residence or concerns about study procedures or side effects. ITO can also streamline and automate processes, enhancing data management and trial design, contributing to more effective drug development.

Patient and site groups

When the patient voice is not sufficiently integrated into the planning stage, patients are not retained in the study or fail to enroll in the first place. ITO ensures they are heard and motivated to participate fully in the study. Rapid surveys, interviews, trial simulation and close collaboration with patient advisory boards (PABs) can offer vital patient and site insights and boost retention.

Market access

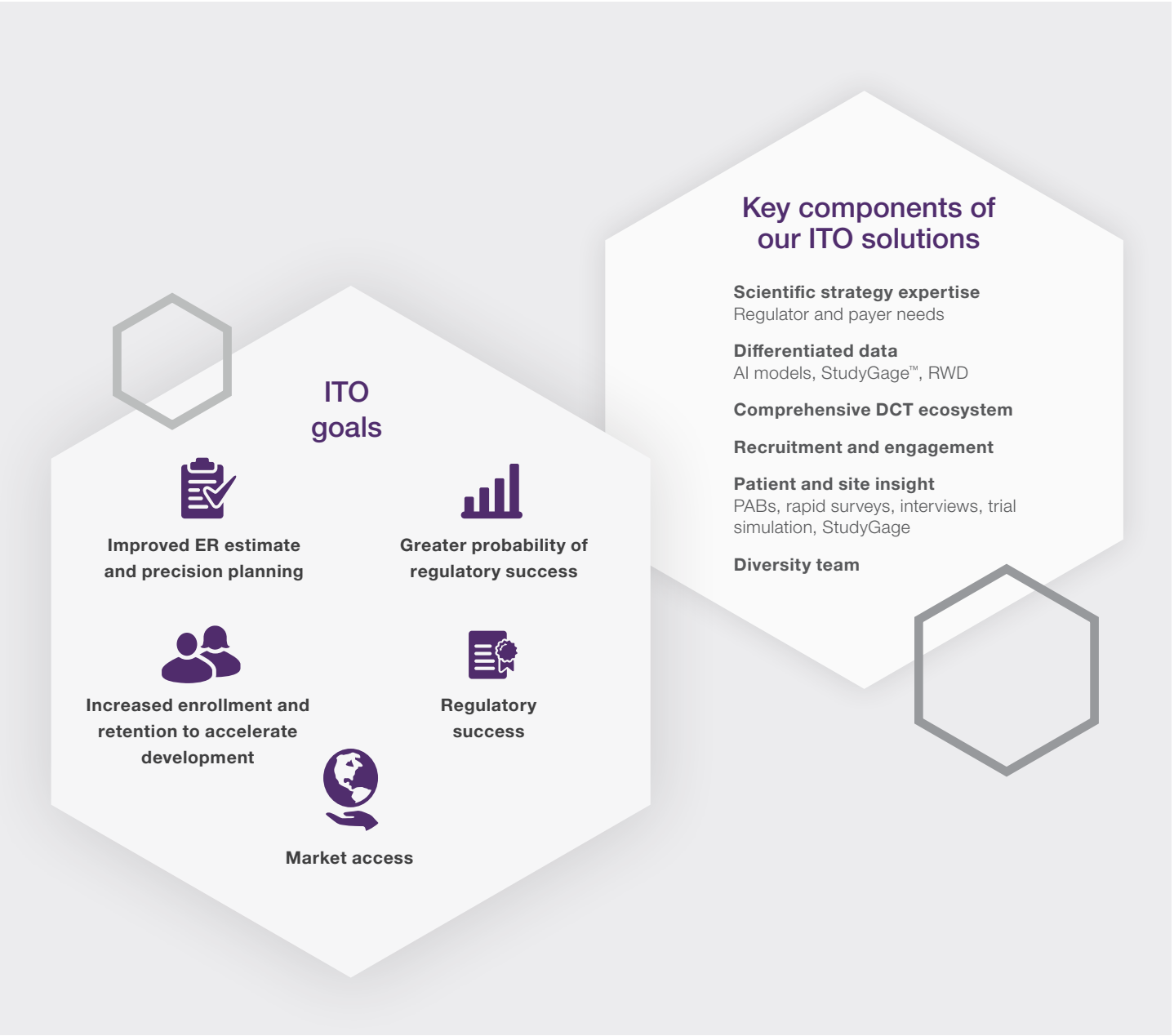
Integrating strategic market access thinking early in the development process, including pre-clinical research and trial design, ensures that payer and regulator needs are addressed sooner. Defining the value proposition early allows for the identification of relevant endpoints and outcomes for payers and patients. It also helps in identifying potential barriers to access and developing strategies to overcome them proactively.

Trial design considerations
✓ Regulator's needs
✓ Site needs
✓ Patient needs
✓ Payer needs
✓ Budget/timelines

Addressing current challenges with ITO solutions

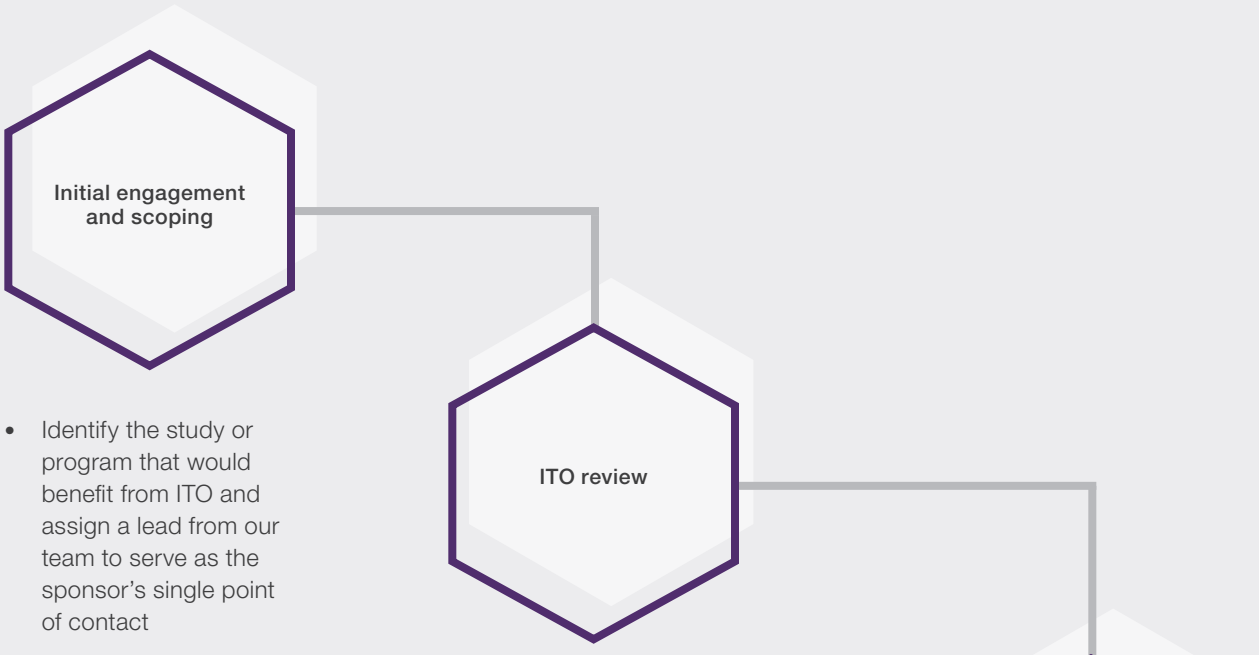
Overview of our ITO solutions

Our breadth of solutions, the result of close collaboration between multiple functions of Thermo Fisher Scientific—including scientific strategy, patient insights, recruitment and feasibility—allows us to tailor ITO to meet client needs.



ITO delivery process flow

With the key inputs provided, we can ease the sponsor's burden by coordinating all relevant expertise to bring about recommendations quickly and to client timelines. With exceptional design and performance, we can simplify and streamline the process.



- Identify the study or program that would benefit from ITO and assign a lead from our team to serve as the sponsor's single point of contact
- Align on the project scope and build a custom package based on selected opportunities

- ITO lead oversees completion of work and management of timelines
- The PPD ITO services team reviews and provides feedback to the ITO lead, making any necessary provisions to deliverables
- A meeting with sponsor teams is held to discuss ITO outputs and recommendations

- ITO lead works with team to update and iterate ITO based on sponsor feedback
- Presentation to sponsor and agreement on final ITO recommendation

StudyGage:

Impact of operational strategy on patient participation

Background

This clinical trial focused on assessing the safety and efficacy of a treatment for COPD. The PPD ITO services team was engaged during the protocol development phase to optimize the clinical trial design, aiming to increase the enrollment rate (ER), reduce timelines and costs, and minimize the risk of amendments that could cause delays.

Challenge

In addition to the typical timeline pressures associated with COPD, the sponsor needed to complete the study within 36 months. Traditional methods would require adding more lower-performing and costly sites to meet this deadline.

Impact

The implementation of ITO resulted in a 9% reduction in the number of sites needed, saving 5% of the study budget. Without ITO, 267 sites would have been required over 36 months based on common feasibility approaches. By formally integrating the operational strategy to improve patient willingness to participate, the team achieved better enrollment rates and reduced the site footprint. Consequently, deadlines were met and the study outcomes were stronger.

Solution

Initial engagement and scoping
Our team assigned a single point of contact throughout the process to ensure alignment with the sponsor on how ITO would be applied. A meeting was held to establish a clear understanding between both parties.

ITO review
The ITO lead managed the timelines and supervised the completion of the work while the team conducted the ITO review. StudyGage, our proprietary study patient burden tool, was used to evaluate the impact of operational strategies on patient participation within an accelerated solution setting. This analysis allowed the team to forecast higher enrollment rates with the proposed strategies. Recommendations were then discussed with the sponsor team.

ITO iteration and final recommendation
The lead oversaw updates and iterations of the ITO, incorporating feedback from the sponsor. Once the final recommendations were agreed upon, the plan was set in motion.

PPD's ITO solution	Case Study
Scientific strategy expertise Regulator and payer needs	
Differentiated date Truecast, StudyGage	
Comprehensive DCT ecosystem	✓
Recruitment and Engagement	✓
Patient and Site insight PABs, rapid surveys, interviews, Trial simulation, StudyGage	✓
Diversity team	✓

Stage	Solution deployed	ER (p/s/m)	Sites	Timeline
Prior study experience		0.9		
Preliminary scope: Covid impacts, select high performing sites	Clinical expertise, site survey Truecast, TriNetX	0.129	184	48m
Base strategy: Expand site footprint	Truecast, TriNetX	0.122	267	36m
Accelerated solutions: Add operational strategy considerations	Operational expertise (DCT, concierge, stipends), StudyGage, Truecast	0.134	244	36m

Thermo Fisher SCIENTIFIC

Learn more at **ppd.com/digital**

ppd