

Smart packaging services

Gain confidence in clinical trial outcomes

Improve adherence to study protocols with smart packaging solutions

Recent guidance from the US Food and Drug Administration (FDA) on enrichment strategies for clinical trials encourages the use of smart packaging technologies as a tool to more accurately understand a patient's exposure to the study drug.¹ A common barrier to adopting smart packaging technologies is the acceptance of the data generated. This recent guidance, along with increasing encouragement by regulatory agencies to better measure medication adherence, elevates the opportunity to leverage smart packaging and devices to enrich clinical trials. Integrating smart packaging solutions into clinical trial strategies can improve medication adherence to dosing protocols and provide a comprehensive understanding of a patient's exposure to the study drug.

Integrating smart packaging solutions into clinical trial strategies can improve medication adherence by ~20% using dosing histories to support patient feedback.²

Simple implementation of smart packaging solutions

Evaluating and onboarding new vendors to implement a new technology can be daunting. The team at Thermo Fisher Scientific has over 20 years of experience with smart packaging. This experience leverages our core competency in packaging with expertise in remote monitoring and trial intervention to support the seamless implementation of this technology into clinical trial supply chains. It can take anywhere from six to 12 months to evaluate and onboard new vendors from project initiation to market readiness (Figure 1). Supply chain and smart packaging experts on our pharma services team have prequalified a broad range of flexible solutions to ensure a simple implementation for sponsors. We help accelerate implementation and streamline communication through established contract templates and robust project management to ensure adherence to timelines.

Qualifying vendors in-house

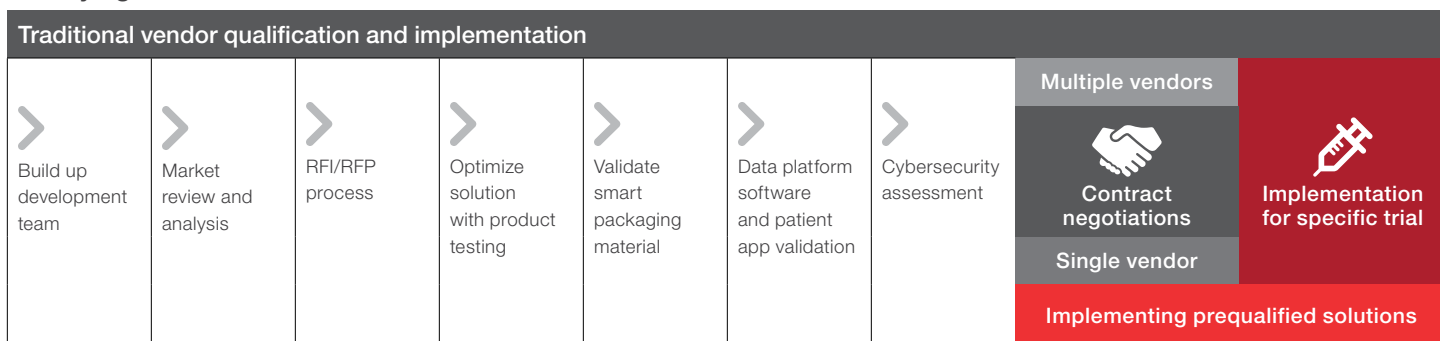


Figure 1. Avoid costly delays and unnecessary effort with prequalified smart packaging solutions. Implementing prequalified solutions eliminates most steps associated with qualifying and onboarding a new vendor to support smart packaging efforts.

Comprehensive smart packaging solutions to achieve medication adherence goals

Selecting the optimal smart packaging solution is a critical step toward achieving medication adherence goals. The optimal smart solution for your trial depends on many variables, such as drug form factor, trial complexity, patient population considerations, and therapeutic area. Integrate smart packaging solutions seamlessly into your clinical supply chain with expert guidance and our dedicated smart packaging innovation laboratory.

Our expanded suite of seven prequalified solutions include hardware such as smart bottles, blisters, and smart labels (Table 1). Data platforms contain easy visual summaries of patient and site data and activity, enabling evaluation of study progress and identification of opportunities for patient intervention (Figure 2).

Table 1. Prequalified smart packaging solutions at a glance. Solutions range from hardware including smart bottles and blisters to digital labels. Select the best solution for your specific study and patient needs.

Smart packaging solution	Smart blister	Smart cap		Smart label
Technology	NFC (RFID)	NFC (RFID)	GSM	Smartphone app
Adherence support by packaging (in addition to app)	None	Visual LCD	Light and sound	N/A
Packaging form factor	Blisters	Bottles	Bottles	Any
Child-resistant option	Yes	Yes	Yes	N/A
Drug form factor	Oral solid dose, parenteral drugs	Oral solid dose, syrup		Any

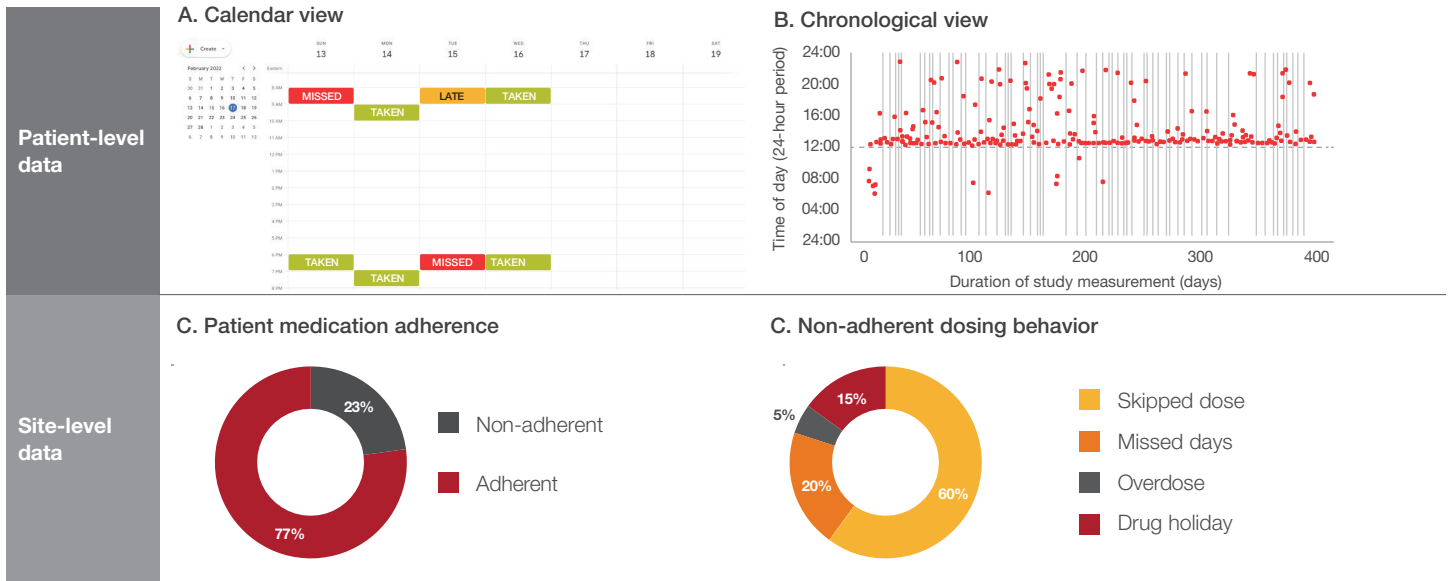


Figure 2. Data visualizations simplify data analysis to provide quick and easy summaries of patient and medication adherence at the subject, site, and trial levels. Easy calendar reminders enabled through smart apps or calendar desktop views can help patients remember medication dosing regimens (a). Clinicians can view individual patient dosing histories to inform patient engagement strategies (b). Data of patient populations at the site (or study) level provide a comprehensive overview of study progress and help clinicians prioritize when patient intervention may be required (c,d).

Complement a decentralized trial strategy with smart packaging solutions

The COVID-19 pandemic has undoubtedly contributed to a fast-growing number of decentralized clinical trials. As patients wish to reduce the number of office visits required for treatment, redirecting trial supplies directly to patient homes is an increasingly powerful strategy to stimulate trial participation. Smart packaging solutions support remote patient monitoring and adherence through remote visibility and reporting. Patients save time through decreased office visits, and clinical sites can prioritize interventions based on adherence dashboards. Thermo Fisher Scientific offers smart packaging solutions in select geographies to complement our direct-to-patient decentralized trial solutions, enabling a patient-centric trial design to meet medication adherence goals (Figure 3).

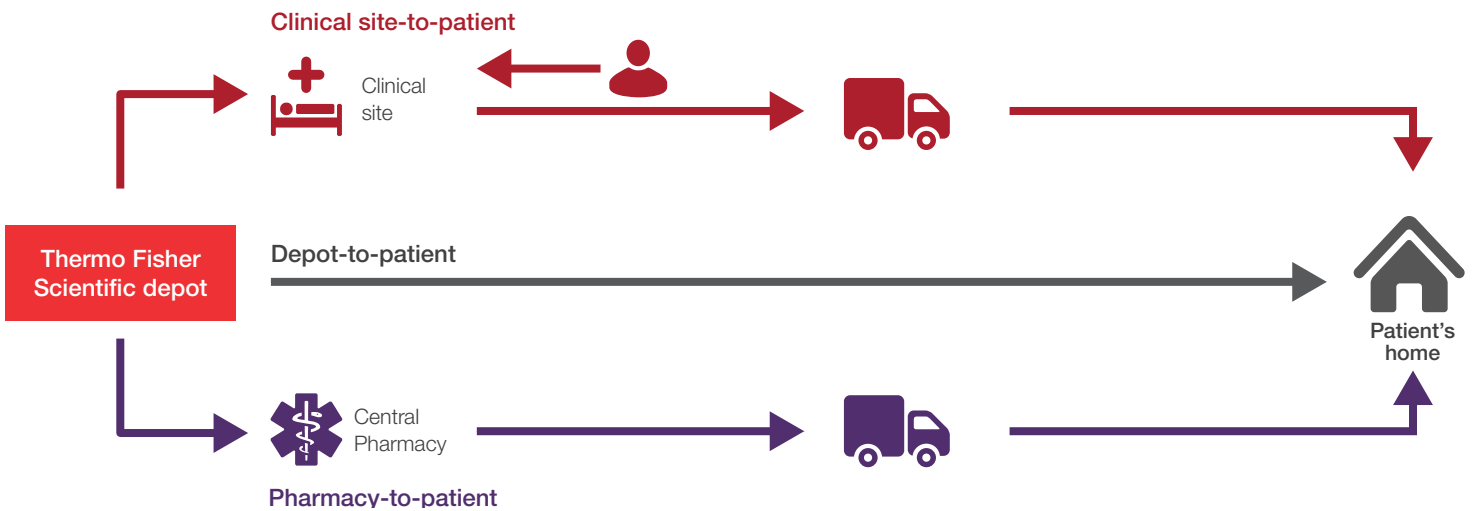


Figure 3. Our direct-to-patient services support improved patient engagement and retention through flexible, decentralized service options. Designed to fit trial formats to patient needs, direct-to-patient services are available in more than 40 countries and have supported over 2,000 shipments to patients worldwide across 25 different therapeutic indications. Clinical site-to-patient services are available worldwide. Depot-to-patient services are available across the United States and in select countries. Pharmacy-to-patient services are enabled across the United States and in European countries.

Integrate smart packaging into your end-to-end supply chain solution

Whether the choice is traditional packaging or a shift to smart packaging to achieve medication adherence goals, Thermo Fisher Scientific has flexible end-to-end solutions to ensure a 360-degree view of the clinical supply chain.



Traditional packaging

- Thermo Fisher can support non-digital primary and secondary packaging needs
- Procure smart packaging solutions directly and engage with Thermo Fisher for traditional packaging services



Smart packaging

- Leverage prequalified smart packaging solutions
- Thermo Fisher provides contracting services, project management, and expertise to help you set up and coordinate your smart packaging implementation



Integrated supply chain solutions

- Integrated packaging solutions for comprehensive, end-to-end clinical trial supply chain support including over-encapsulation, primary and secondary packaging, and bottling and labeling
- Supporting all phases of development to deliver a 360-degree view of the clinical supply chain

Improve medication adherence in your next clinical trial.²

Contact your local Thermo Fisher Scientific representative to learn more.

1. US Department of Health and Human Services, Food and Drug Administration (March 2019). Enrichment strategies for clinical trials to support determination of effectiveness of human drugs and biological products: guidance for industry. <https://www.fda.gov/media/121320/download>.

2. Identification and Assessment of Adherence-Enhancing Interventions in Studies Assessing Medication Adherence Through Electronically Compiled Drug Dosing Histories: A Systematic Literature Review and Meta-Analysis. *Drugs* (2013) 73:545–562. DOI 10.1007/s40265-013-0041-3.

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or email us at pharmaservices@thermofisher.com
or call **+1 919 226 3200**