Whitepaper

MAXIS
CLINICAL SCIENCES

How Will Embedded FSP Partnerships Change Sponsor-Vendor Collaboration in Clinical Trials?

Clinical trials are becoming more expensive and complex, pushing pharmaceutical companies to find better ways to manage their research. As **Maik Jornitz**, President and CEO of G-CON, aptly put it, **"Nobody wants to be the first to try something new; everybody wants to be the fastest second."** This captures the industry's need to balance innovation with practical solutions. That's why more companies are moving from traditional outsourcing to technology driven Functional Service Provider (FSP) partnerships.

However, rapid growth brings its own set of hurdles—complex trials, strict regulations, and tight deadlines. To solve these problems, many companies are moving from the traditional outsourcing model to the technology integrated FSP model[1]. These partnerships emphasize deep collaboration and shared responsibility the same way they do strategic alignment in the long term and the use of technologies to automate processes and accelerate trials.

This white paper explores how technology integrated FSP partnerships are changing the game in clinical trials, offering sponsors the flexibility and innovation they need to succeed in today's fast-paced research landscape.

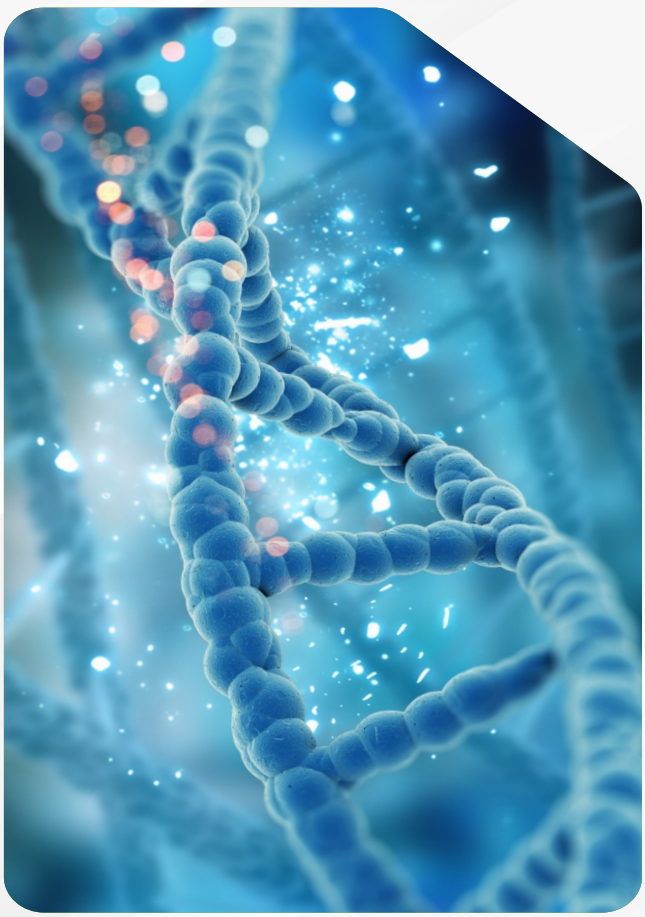
Are FSP Partnerships the Answer to Complex Clinical Trials?

Running clinical trials is getting harder. Sponsors are struggling to keep up with the increasing complexity and need more efficient ways to manage everything. Traditional outsourcing often falls short because it can be too rigid, create communication issues, and lack the specialized expertise needed for today's trials[2]. These limitations can make it tough to respond quickly and stay flexible, especially when deadlines are tight, and regulations are strict.

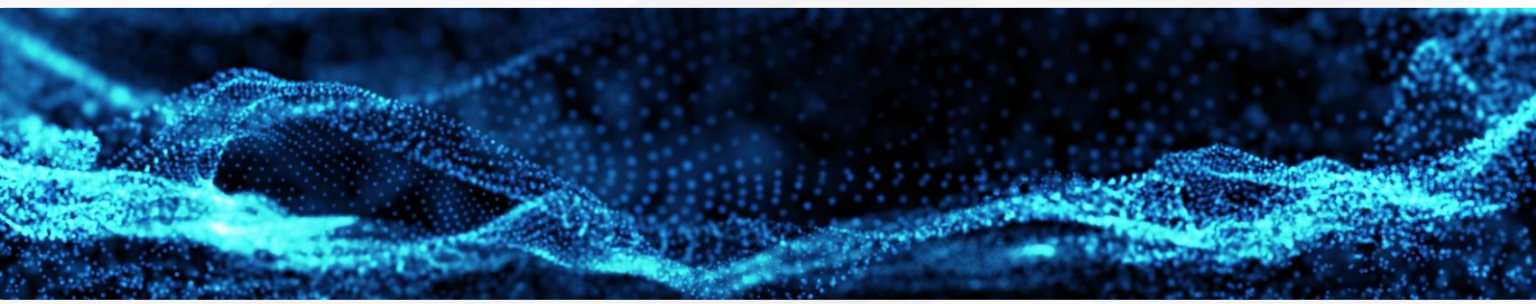
That's why FSP models have become a popular option. They give sponsors the flexibility and access to specialized expertise they need. By offering customized solutions and support that can be scaled up or down as needed, FSP partnerships allow sponsors to focus on their specific trial needs without sacrificing quality or efficiency[3]. In fact, FSP adoption has been growing faster than traditional outsourcing in recent years[2].

Now, the next generation of FSP partnerships is changing how sponsors and vendors work together. Instead of keeping vendors at arm's length, these collaborations embed vendor staff directly within sponsor companies. This leads to better collaboration, joint decision-making, and alignment on strategy. By acting as an extension of the sponsor's team, vendors help drive operational efficiency and long-term success[3].

Tech-enabled FSP models are the latest step forward. These models use advanced technologies to make trial processes even better. From risk-based monitoring (RBM) to AI-driven analytics and automation, these innovations improve data accuracy, streamline workflows, and speed up timelines. By combining strong partnerships with practical technology solutions, clinical trial management becomes easier and more reliable, giving sponsors the support they need to handle complex trials with confidence and speed.



Aspect	Traditional Outsourcing	Basic FSP	Tech-Enabled FSP
Integration Level	Arm's length relationship	Embedded teams	Fully integrated with tech backbone
Decision Making	Separate processes	Joint governance	AI-assisted collaborative decisions
Technology Use	Basic tools	Standard platforms	Advanced AI, automation, predictive analytics
Scalability	Limited flexibility	Moderate scaling	Dynamic resource allocation
Risk Management	Reactive approach	Risk-based monitoring	Predictive risk identification



What Exactly Is a Tech-Enabled FSP Model?

Think of a Tech-Enabled FSP model as a way to get the best of both worlds. It's a mix of top-notch clinical trial know-how and a personalized approach for each partner. Sponsors gain access to skilled people, the latest technology, and a solid infrastructure, helping them run their trials better and hit their goals efficiently[1].

The idea behind these partnerships is simple: bring sponsors and vendors closer together. Instead of working separately, vendor teams become like an extension of the sponsor's own team, working directly within their systems. This close integration makes it easy to share data and work together smoothly. Using advance technology to handle routine tasks and give up-to-date information helps these teams work faster, reduce mistakes, and adjust quickly when things change. This way, the whole clinical trial process becomes easier and more effective. This boosts collaboration and makes everything run more smoothly. As **McKinsey and Company** has pointed out, *when vendor teams are truly embedded within the sponsor's operations, it streamlines processes and cuts down on delays caused by miscommunication*.

Another key part of the Tech-Enabled FSP model is **shared decision-making**. Through things like joint steering committees and clearly defined, mutual objectives, both vendors and sponsors stay accountable and make sure they're aligned.

Boston Consulting Group (BCG)

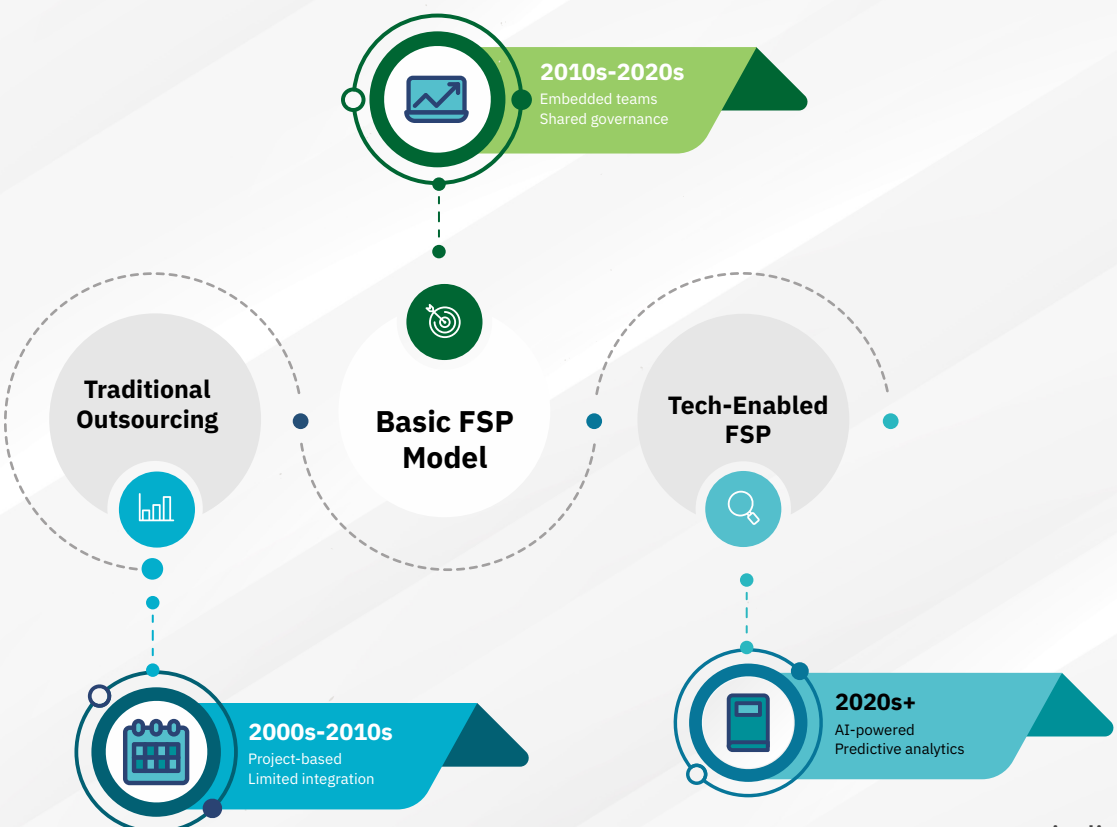
has found that *this kind of shared governance*

can speed up decision-making by as much as

30%

- *which helps avoid bottlenecks*
- *and builds trust.*

Unlike traditional outsourcing, which focuses on one project at a time, Tech-Enabled FSP partnerships encourage collaboration across the **entire pipeline of trials**. This leads to ongoing innovation and helps sponsors expand their capabilities efficiently without compromising on quality. *McKinsey's research shows that this approach improves scalability and resource optimization, especially in complex therapeutic areas.*



Key Characteristics of Tech-Enabled FSP Models

1. Technology Integration

The most prominent features of tech-enabled FSP models are automated workflows, automated processes, and AI-powered predictive analytics. Such technologies automate additional tasks, reduce manual input, and expedite timeframes. For example, **MaxisIT's Site Copilot** is a conversational AI agent that integrates directly into site operations to help staff detect and manage quality, compliance, and patient engagement risks in real time [4]. By providing AI-powered recommendations, automated risk and quality scoring, and actionable insights through natural language conversations, Site Copilot streamlines workflows and improves collaboration between sponsors and sites—leading to faster site activation and more reliable trial execution. Tools like this have been shown to significantly reduce site assembly timelines and optimize site selection, demonstrating the practical benefits of technology integration in clinical research.

2. Proactive Risk Management

Predictive analytics enable early identification of risks, allowing sponsors to address challenges before they impact trial progress. This proactive approach minimizes disruptions and ensures smoother execution.

According to BCG, predictive technologies have reduced process costs by up to

- Improves data quality
- Enhances signal detection
- Critical for trial success

3. Operational Efficiency

Increased automation decreases cycle time for data processing and reporting, increasing the speed at which trials can be conducted while maintaining quality. Real-time views of trial data are possible through consolidated IT applications, which are free of any manual input, thus improving productivity. For example, **Centralized monitoring systems** have enabled instant data harmonization compared to traditional processes that often take 24–48 hours.

4. Cost Optimization

With the use of centralized delivery models and the flexible allocation of resources, sponsors are able to cut costs effectively without sacrificing quality or deadlines. As research shows, decentralized trials with scalable tech infrastructure further reduce patient burden while still **sustaining integrity**—one of the primary pillars of modern clinical research.

Tech-enabled FSP models mark the start of a new era in the management of clinical trials. By combining technology-driven innovation with strategic collaboration, these partnerships empower sponsors to navigate complexity with agility and precision. Supported by insights from top firms like **McKinsey and BCG**, these models are changing their approach to design more efficient clinical trials in response to the growing research demands.

The Role of Technology in FSP Partnerships

As the clinical trials grow more complex, becomes crucial to integrate the right technologies with FSP partnerships. Today's sponsors are looking not for transactional support but strategic partnerships that combine **deep functional expertise with advanced intelligent systems** capable of adapting to changing research demands. This is where other Tech-Enabled FSP models, are most beneficial.

Let's look at how some key technologies are improving the FSP delivery and transforming the collaboration between the sponsors and the vendors.

1. Artificial Intelligence & Machine Learning: Predictive Precision in Clinical Development

AI and machine learning significantly improve the effectiveness of a trial's efficiency and foresight. These technologies scan both historical and real-time data for insights that could lead to delays or issues, such as identifying site delays, patient dropouts, and protocol deviations before they cause any major issues.

In the Tech-Enabled FSP model, AI is used to:

- **Foster proactive** site and patient management by predicting enrollment changes.
- **Support adaptive trial designs,** which adjust in response to early findings, improving both speed and accuracy.
- **Enhance risk-based monitoring,** which ensures resources are allocated to the areas where they are most needed.

This promotes data-driven decision-making in trial management in a more proactive manner, where decisions are automated in real time instead of months later.

2. Centralized Technology Platforms: Creating a Single Source of Truth

One of the greatest challenges in sponsor-vendor partnerships is **Data Fragmentation**. Centralized platforms are capable of solving this issue by allowing both sponsors and FSP teams to collaborate, access real-time data, and monitor cross-functional performance.

These platforms support:

- **Real-time data sharing** between stakeholders.
- **Integrated dashboards** for KPIs, milestones, and issue tracking.
- **Improved governance and audit readiness,** with traceable activity logs and document version control.

In this context, the platform isn't just a communication tool—it becomes the backbone of an **integrated delivery model** that enables transparency, accountability, and faster decision-making.

3. Automation: Streamlining Processes, Reducing Burden

Automation is critical for scalability and consistency in clinical operations. Traditionally, processes such as query resolution, document indexing, and compliance tracking are performed manually, leading to errors and inefficiencies.

With automation, the Tech-Enabled FSP model can:

- **Accelerate data cleaning and validation** through automated checks.
- **Reduce manual errors** by standardizing repeatable processes.
- **Increase productivity,** freeing up functional experts to focus on more strategic work.

Importantly, automation doesn't replace human expertise—it complements it by allowing teams to work **smarter and faster,** without compromising on quality or compliance.

Technology as a Catalyst for Sponsor-Vendor Integration

What truly sets the Tech-Enabled FSP model apart is not just the technology itself, but **how seamlessly that technology is embedded into the delivery framework.** This deep integration of digital tools into day-to-day functional operations is what enables **more transparent, efficient, and collaborative relationships** between sponsors and service providers.

Technology Integration Area	What It Enables	Impact on Sponsor–FSP Collaboration
Centralized Clinical Platforms	Shared dashboards, real-time data access, unified workflows	Transparency, reduced miscommunication, aligned decision-making
AI & Predictive Analytics	Enrollment forecasting, site performance trends, risk signals	Informed, proactive trial management by both sponsor and FSP teams
Cloud-Based Document Systems (eTMF)	Version control, audit trails, seamless documentation	Faster reviews, consistent compliance, simplified inspections
Automated Query & Issue Resolution	Workflow triggers and auto-routing for faster response times	Increased speed, fewer delays, improved operational coordination
Integrated Performance Dashboards	Real-time KPIs across functions	Shared ownership of outcomes, easier course correction
Cost Optimization	Eliminates redundant tasks, streamlines data, reduces errors and delays	Lower operational costs, improved resource allocation, higher ROI

"Sponsors who leverage integrated digital tools in outsourced trials report a 21% improvement in trial efficiency."

— Tufts CSDD, 2023

Benefits of Tech-Enabled FSP Partnerships

Tech-Enabled FSP models are redefining how sponsors approach outsourcing by integrating domain expertise with embedded technologies that drive transparency, agility, and smarter execution. This next-generation partnership model isn't just about doing more with less — it's about **working better, together.**

Here's how technology translates into measurable benefits across clinical development.

1. Enhanced Collaboration

At the core of any successful FSP partnership is collaboration — and technology is what makes it scalable, structured, and seamless.

- **Integrated workflows and shared systems** remove the barriers between sponsor and FSP teams, ensuring that both operate from a single source of truth. When both parties have real-time visibility into tasks, timelines, and data, coordination becomes second nature.

- **Real-time communication and data sharing** allow for immediate issue resolution and tighter alignment on study milestones. These tools foster greater trust and enable joint ownership of outcomes — a shift from vendor execution to true partnership.

According to research, 89% of life sciences companies believe that shared platforms are key to improving sponsor-provider collaboration and speeding up trial execution.

2. Operational Efficiency

The integration of automation and centralized systems within FSP operations eliminates inefficiencies that have historically slowed down trials.

- **Automated processes** like query routing, document indexing, and risk alerts reduce manual burden, freeing teams to focus on higher-value strategic work

- **Centralized platforms** reduce redundancy, ensure data consistency, and simplify regulatory readiness by maintaining a clear audit trail.

The result is faster trials, fewer corrections, and sustained regulatory alignment.

3. Scalability

The ability to scale intelligently without sacrificing quality is a significant benefit of tech-enabled models.

- **Dynamic resource allocation tools** allow FSP teams to adjust staffing based on real-time workload projections, ensuring that sponsors always have the right expertise at the right time.

- With visibility across therapeutic areas and geographic regions, **specialized talent** can be deployed efficiently, ensuring continuity even in large or rapidly evolving portfolios.

This is particularly critical for biotech and mid-sized pharma companies looking to grow without the overhead of internal hiring surges.

4. Improved Trial Outcomes

Enhanced collaboration and efficiency improve clinical outcomes.

- **Accelerated study start-up times,** supported by pre-built workflows, pre-qualified vendors, and automated documentation, help trials start strong.

- **Enhanced compliance monitoring** and real-time tracking reduce the risk of deviations and inspection findings, leading to smoother submissions and faster approvals.

In a recent survey by the **Tufts Center for the Study of Drug Development,** sponsors using tech-integrated FSPs reported **15–25% faster study start-up times** and fewer regulatory hold-ups compared to traditional models.[5]

The tech-enabled FSP model is a **strategic enabler of performance, agility, and clinical success.** For

sponsors aiming to accelerate progress without sacrificing control, this model offers an optimal blend of innovation and execution.

Overcoming Challenges with Tech-Enabled FSP Solutions

Challenge 1: Resource Constraints

The lack of access to experienced talent has hampered many sponsors' ability to conduct critical functions like biostatistics and data management in a timely manner, adversely affecting study timelines and data quality. For instance, biostatisticians play a vital role in optimizing trial design, minimizing costs, and accelerating timelines by using adaptive methodologies and precise protocol development[6].

Solution: FSP models powered by advanced technologies deploy specialized experts directly into sponsor workflows. These professionals integrate seamlessly with existing teams, ensuring efficient delivery of high-quality results. Additionally, technology-enabled solutions such as automated processes and AI/ML tools further enhance productivity, enabling sponsors to meet tight timelines without sacrificing quality[1].

Challenge 2: Disparate Systems

Fragmented systems for clinical data collection and analysis create inefficiencies, increase errors, and complicate regulatory submissions. For example, the lack of standardized data formats can hinder cross-study comparisons and regulatory compliance[7].

Solution: FSP solutions leverage centralized platforms that unify clinical data across trials. These platforms standardize processes in line with global standards such as CDISC Foundational Standards, reducing errors, and improving data integrity[7]. Advanced FSP features including AI-driven analytics, metadata management, real-time performance monitoring, and dynamic resource allocation, empowering sponsors to optimize workflows and enhance decision-making[7]. By harmonizing disparate systems with these intelligent technologies, sponsors achieve greater efficiency, scalability, and cost-effectiveness in data collection and reporting.

Challenge 3: Regulatory Compliance

Global trials require adherence to complex regulatory standards, which can be resource-intensive and challenging to manage. For example, implementing risk-based quality management (RBQM) frameworks has become increasingly essential to ensure compliance with international guidelines like ICH GCP E6(R2)[8].

Solution: FSP teams apply RBQM frameworks that help identify risks early and ensure compliance with international regulations. These frameworks use tools like centralized statistical monitoring and predictive modeling to keep trials on track and maintain quality[8]. In addition, vendors provide smart regulatory platforms, often powered by AI, that keep sponsors updated on evolving guidelines and help organize and check regulatory information automatically. These AI-driven tools reduce manual work, minimize errors and standardizing formats according to global regulatory requirements. This helps sponsors understand regulatory requirements faster, and submit documents more quickly, making it easier to manage complex rules.

Use Cases of FSP Solutions from Maxis Clinical Sciences

Use Case 1: Accelerating Study Start-Up Times for a Biotech Company

- **Scenario:** A small to mid-sized biotech company is launching a Phase II trial for a new cancer treatment. They need to start quickly to meet milestones but don't have enough internal staff to quickly find, approve, and activate trial sites.
- **Challenge:** Traditional outsourcing is slow and requires a lot of oversight, which delays the trial's start.
- **Solution with Tech-Enabled FSP:** The company partners with an FSP that uses a technology-integrated model. This includes:
    - **Smart Site Selection:** The FSP uses data analysis to find good trial sites with the right patients and experienced doctors.

  - **Automated Processes:** Automated steps for approving sites, negotiating contracts, and submitting paperwork speed up the start-up process.

  - **Central Platform:** A shared online space provides a clear view of start-up activities, allowing the company and the FSP to work together and fix problems quickly.

- **Outcome:** The study starts 15-25% faster than with traditional methods, helping the company meet its goals, get more investment, and bring the treatment to patients sooner.

Use Case 2: Improving Operational Efficiency and Data Quality in a Complex Global Trial

- **Scenario:** A company is running a large, international Phase III trial for a heart drug. The trial has many sites, complex plans, and lots of data, creating challenges in keeping data accurate, consistent, and running the trial efficiently.

- **Challenge:** Scattered data, manual steps, and different systems lead to mistakes, delays, and higher costs.

- **Solution with Tech-Enabled FSP:** The company partners with an FSP to use a technology-integrated solution:

  - **Central Clinical Platform:** A single online space combines data from different sources, providing one reliable place for all information.

  - **Smart Data Analysis:** Data is monitored to spot potential risks, plan problems, and data errors early on.

  - **Automated Problem Management:** Automated steps for fixing data problems speed up the data cleaning process and ensure data is correct.

- **Outcome:** The company has fewer data errors, faster problem-solving, better data quality, and increased efficiency. This leads to better trial results, smoother regulatory submissions, and significant cost savings.

Use Case 3: Enhancing Compliance and Reducing Risks in a High-Stakes Regulatory Environment

- **Scenario:** A company is preparing to submit data to regulatory agencies for a new treatment in a highly regulated market. The submission needs careful documentation, following strict rules, and strong risk management.

- **Challenge:** Manual steps and scattered systems increase the risk of breaking rules, regulatory delays, and potential rejection.

- **Solution with Tech-Enabled FSP:** The company works with an FSP that offers technology-supported compliance solutions:

  - **Online Document Systems:** A central online system ensures correct versions of documents, tracks changes, and provides smooth documentation.

  - **Risk-Based Monitoring:** Monitoring tools and data analysis help find potential risks and compliance problems early.

  - **Integrated Performance Tracking:** Real-time tracking of key performance indicators (KPIs) provides transparency and allows for quick adjustments.

- **Outcome:** The company achieves better compliance, reduced risks of regulatory issues, and smoother submissions. The treatment gets approved faster, benefiting patients and improving the organization's reputation as reliable and compliant.

Challenge: Resource Constraints

Limited access to specialized talent like biostatisticians affecting study timelines and data quality

Solution: Specialized Expert Deployment

AI/ML-enhanced FSP teams integrate seamlessly with automated processes for high-quality delivery

Challenge: Disparate Systems

Fragmented data collection creating inefficiencies and regulatory compliance issues

Solution: Unified Platforms

CDISC-compliant centralized platforms with AI-driven analytics and real-time monitoring

Challenge: Regulatory Compliance

Complex global standards requiring resource-intensive management

Solution: RBQM Frameworks

AI-powered regulatory platforms with automated compliance checking and real-time guidance

Vendor Spotlight: Maxis Clinical Sciences' Comprehensive FSP Solutions

Maxis Clinical Sciences stands out as a trusted partner in the clinical research space, offering tailored FSP solutions that seamlessly integrate into sponsor workflows. Beyond tech-enabled FSP **(MaxisAdvance)** partnerships, Maxis provides a diverse range of FSP models designed to meet the unique needs of sponsors across therapeutic areas and trial phases, each designed to address specific requirements:

MaxisAgile: Offers on-demand expert staffing for immediate and short-term project needs, ideal for addressing resource constraints.

MaxisFlex: A hybrid model combining dedicated staffing with flexible resource allocation to adapt to evolving project demands.

MaxisSync: Managed workforce solutions that provide end-to-end oversight of project tasks and timelines.

MaxisTotal: A fully outsourced FSP model where Maxis takes complete responsibility for specific functional areas, ensuring seamless delivery.

Future Directions for Tech-Enabled FSP Models

AI-Powered Analytics

The integration of AI-powered analytics will redefine clinical trial processes by optimizing trial design, patient recruitment, and risk management. Advanced algorithms can analyze vast datasets to identify patterns, predict outcomes, and streamline decision-making. For example, predictive analytics can enhance patient matching based on genetic profiles or medical histories, improving recruitment efficiency and trial success rates[9].

Decentralized Trials

The combination of built-in FSP partnerships with decentralized elements results in a blended approach. These new models make it easier for participants to take part while protecting the integrity of data collected. Things like eConsent, telehealth, and other wearables can be utilized in the study to reduce patient burden and enhance engagement. Such flexibility allows trials to adapt to therapeutic areas and study goals effectively.

Patient-Centric Technologies

Patient-centric technologies will play a pivotal role in capturing real-world evidence and improving trial relevance. Platforms that integrate digital biomarkers, smart dosing systems, and real-time data visualization will enable better understanding of patient experiences. This approach not only reduces patient burden but also accelerates recruitment and enhances trial outcomes, particularly in challenging therapeutic areas like oncology and rare diseases[10, 11].

Faster Regulatory Submissions and Approvals

Tech-enabled FSP models are making the regulatory submission process quicker by automating how documents are prepared, making sure data is checked thoroughly, and following the latest rules. Automated systems cut down on mistakes and check data in real time, so submissions are more accurate and complete. This means quicker review times and faster responses to questions from regulatory agencies, helping new treatments get approved and to patients sooner [12].

AI-Powered Analytics

Advanced algorithms for trial optimization and predictive outcomes

Decentralized Trials

Hybrid models with eConsent, telehealth, and wearables

Patient-Centric Tech

Digital biomarkers and real-time data visualization

Faster Approvals

Automated submissions and real-time regulatory compliance

Recommendations for Sponsors

To maximize the benefits of tech-enabled embedded FSP partnerships, sponsors should consider the following:

1. Assess Operational Gaps:

Conduct a comprehensive assessment of areas where technology can add value, such as data management or patient recruitment.

2. Choose Proven Vendors:

Partner with experienced providers that specialize in tech-enabled solutions.

3. Establish Governance Frameworks:

Define clear accountability structures to ensure seamless collaboration across integrated teams.

4. Invest in Centralized Platforms:

Adopt platforms that facilitate efficient communication and data sharing between internal teams and external partners.

5. Foster Innovation:

Encourage a culture that embraces automation, predictive analytics, and other advanced technologies to optimize trial processes.

6. Adopt Smart Technology:

Look for and use tools that help simplify tasks, improve data review, and support better decisions. Focus on solutions that can help design trials more effectively or find the right patients faster to improve recruitment.

Conclusion

The future of clinical trials lies in utilizing technology-driven FSP models that integrate AI, decentralized methods, and patient-centric approaches. By adopting these innovations, sponsors can overcome traditional challenges, improve trial efficiency, and deliver better outcomes for patients worldwide.

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