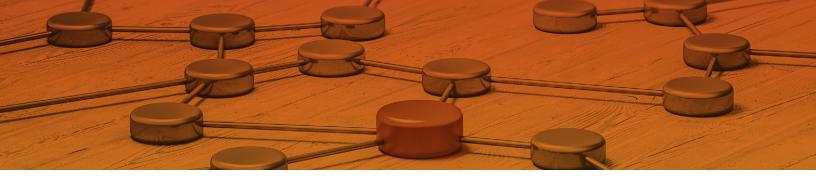


With market pressures and regulatory environments constantly shifting, along with a movement toward consolidating outsourced clinical solutions, typical static functional service provider (FSP) models may no longer meet your needs.

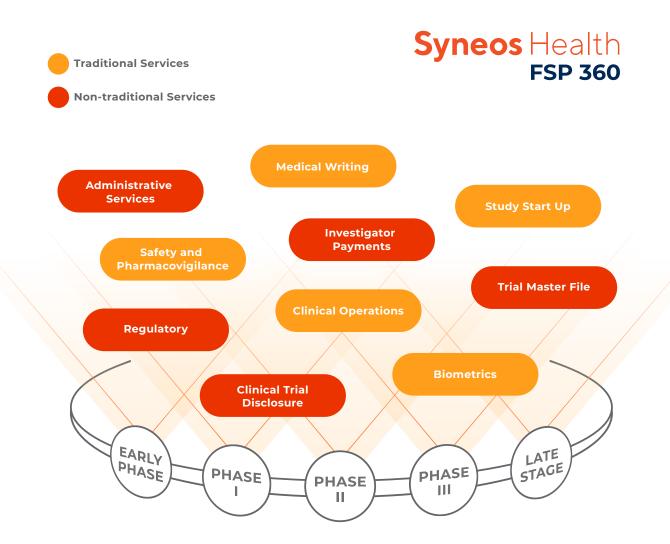
# Every sponsor is unique.

We believe every FSP solution should be too.



Syneos Health® has developed FSP 360 to provide the broadest range of traditional service functions, as well as many non-traditional functions not usually offered as an FSP.

Through a unique and dynamic approach, we can customize solutions to successfully meet your individual needs and goals across your entire asset portfolio.



Syneos Health can provide an array of FSP 360 services anytime during the clinical development life cycle

## Why Choose FSP 360?

At Syneos Health, we approach clinical development with a 360-degree view, enabling our experts to fill gaps at any time during your clinical development program and help identify any blind spots that may need attention. Engagements can be scaled based on where you are in your outsourcing strategy. We can apply fit-to-purpose solutions ranging from accessing functional excellence to quickly meet specific project-based needs to a multifunction FSP providing a combination of traditional and non-traditional services. FSP models are moving from scale toward specialization. With our FSP 360 approach, we help customers improve the FSP models of today to lay the foundation for tomorrow.

The FSP 360 model can stand alone or be used in combination with a full-service outsourcing approach. When combined with Syneos Health's best-in-class Commercial Solutions, including consulting, regulatory and market access capabilities, we can further optimize customer outcomes.

With our FSP 360 approach, we help customers improve the FSP models of today to lay the foundation for tomorrow."



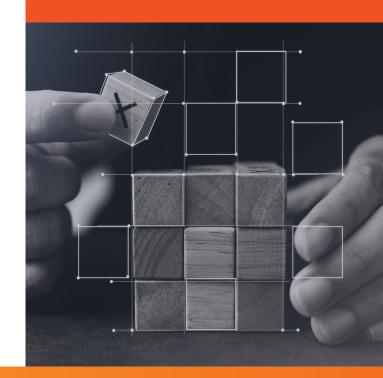
22 Years of Experience



5,000+ Global FSP Staff



70 Partnerships in 53 Countries



## **Syneos Health FSP Services**

## Traditional Services

# CLINICAL OPERATIONS

- Clinical Monitoring
- Risk-Based Monitoring Enablement
- Centralized Data Review
- Program and Project Management

#### SAFETY AND PHARMA-COVIGILANCE

- Signal Detection
- Case Processing
- Expedited and Periodic Reporting
- QPPV Office Consulting and Support

#### STUDY START-UP

- Site Contracts and Budgets
- Site Ethics and Country Regulatory Submission

#### **BIOMETRICS**

- Data Management
- Biostatistics and Programming
- Medical Writing

#### **MEDICAL WRITING**

- Protocol Design
- Clinical Study Reports and Manuscripts
- Regulatory
   Submission
   Documents

## Non-traditional Services



# INVESTIGATOR PAYMENTS

- Global Investigator Payments
- Sunshine Act/ Transparency and Cash Forecast Reporting
- Patient Reimbursement Services



## TRIAL MASTER FILE

- Electronic and Paper TMF Management
- Independent TMF Inspection Readiness and Compliance Team



# CLINICAL TRIAL DISCLOSURE

- Protocol Registration and Maintenance
- National Registries
- End-to-End Services



## REGULATORY

- Pre- and Postapproval
- Strategy and Intelligence
- Technology



# ADMINISTRATIVE SERVICES

- LMS Support
- CTMS Admin Support and Reporting
- KPI/Dashboard Maintenance

CTMS = clinical trial management system; KPI = key performance indicator; LMS = learning management system; QPPV = qualified person responsible for pharmacovigilance; TMF = trial master file

FSP 360 is an essential component of our Biopharmaceutical Acceleration Model™ (BAM), a comprehensive clinical continuum that delivers what today's customers need most—an end-to-end clinical partner committed to strategic solutions designed to accelerate performance.

#### Want to learn more?

Eleanore L. Doyle, Executive Vice President - FSP 360 Eleanore.Doyle@syneoshealth.com www.syneoshealth.com/solutions/fsp-360

