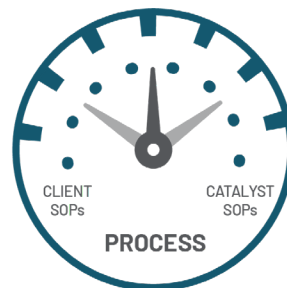# Functional Biometrics solutions

We know that FSP means different things to different people. Designing bespoke biometrics models is our differentiator. We listen to your challenges, requirements, and preferences, then customize our biometrics solutions based on those needs.

We are a dedicated partner that listens to you, then provides the people, processes, and technology solutions to meet your needs. Catalyst Flex is here to help solve your biometrics problems.

INDIVIDUAL RESOURCES — FUNCTIONAL TEAMS

PEOPLE

CLIENT SOPs — CATALYST SOPs

PROCESS

CLIENT TECH — CATALYST TECH

TECHNOLOGY

The Catalyst Flex approach to biometrics provides active participation from the start to finish of your project.

At Catalyst Flex we:
- Focus on quality to build a solid foundation
- Work cohesively with your teams and across functions
- Assign a functional lead to each project
- Require senior leader review of all deliverables
- Ensure study data integrity—from database development to database lock and beyond
- Provide executive oversight for each engagement

Most outsourcing partners can provide a project biometrics team. We deliver biometrics by tapping into our pool of talent—which includes a database of 7,000+ known subject matter experts (SMEs)–and pulling experts to support from a single resource, from a program of studies, or full functional outsourcing.

> *"Catalyst Flex properly identified the resource we needed, aligned with our very short turnaround, and was available to support us."*
> **Catalyst Flex Client**

Innovative approaches to **functional outsourcing**

catalystflex.com

Our solutions range from concept design through database build to regulatory reporting and beyond. With expertise in medical devices, vaccines, and medicinal products across multiple therapeutic areas, Catalyst Flex works with all types of clients, across all phases of development to support information for decision making.

We work with a variety of electronic data capture (EDC) systems and have skilled people working across many platforms. Since we are program-agnostic, we recommend options based on the situation, work with your specific systems, or work together to design a unique technology solution for your needs.

Our forward-thinking use of multiple programming languages means that Catalyst Flex can utilize SAS for statistical programming or program in R, Python, and other open-source languages. Programming is provided on a project basis or Catalyst Flex places SMEs with your team.

Catalyst Flex is also able to provide medical writing and scientific authoring services to help you achieve high-quality results for regulatory, safety, medical, and scientific communications, including health economics and outcomes research (HEOR).

Our offerings incorporate robust and flexible processes, job aids, and guidance that our teams leverage to deliver across therapeutic areas and all phases with one global set of standard operating procedures (SOPs) unless there is a requirement to follow your SOPs.

Additional features we offer include:

- Dynamic visualization capacities to use for ongoing management of a study, such as dosing decisions, monitoring safety of patients, highlight trends/signals in the data
- Pharmacokinetic (PK) analyses for new or ongoing studies
- Partnerships between statisticians and programmers to work closely with experienced medical writers utilizing AI technology

Catalyst Flex Biometrics Services

Data Management

- Vendor - Data Transfer Agreements
- Vendor Reconciliation
- Data Review / Cleaning
- Managing Data Currency & Accuracy
- eCRF Design, Database Development & Validation Across Multiple Platforms
- Medical Coding & Data Reconciliation
- Local/central Lab Management
- Database Lock & Regulatory Submission Files
- EDC Development & Programming
- Edit Check Specification
- User Acceptance Testing
- Development / Support of Data Management-driven Documentation

Biostatistics & Programming

- Adaptive Designs
- Bayesian Methodology
- Statistical Consultancy
- Manuscript & Publication Support
- Trial Design
- Randomization
- SAP & TLF Shell Development
- IB/DSUR/SRC Development
- DSMBs/DMCs/Interim Analysis
- CSR Support
- CDISC Compliant Datasets Documentation
- Legacy Data Integration

Additional Services

- Regulatory Submissions
- Grant Applications

Innovative approaches to **functional outsourcing**

catalystflex.com