Functionally Aligned Strategic Team (FAST)

What is FAST?

Our FAST program is a subset of our FSP outsourcing model and is designed to maximize efficiency, quality, and value in your R&D efforts. The Functionally Aligned Strategic Team is made up of SMEs from a given functional area or areas specifically designed to complement your team and meet the needs of your study, program, or project. The FAST team can include full FTEs and/or fractional FTEs based on the nature of the project.

The FAST program is best implemented when there is a finite and unmet need such as a move from preclinical to early phase clinical research, drafting of a protocol and updating an Investigator Brochure given feedback from a regulatory agency, quality control of data given resource shortages at a CRO, implementation of an inspection readiness plan, drafting SAE narratives in support of a NDA.

How it Works:

A lead Strategy Advisor from Harbor Clinical will meet with you and your team to gain an understanding of the specific needs and goals. With that, a proposal is quickly developed and presented. Depending on the scope of the project, our FAST will be in place in a matter of days. A lead point person is assigned and, where appropriate, a governance structure is established. We will design and propose the right level of governance for the project, bearing in mind that the FAST program may be implemented on projects small or large projects.

Strategy Session:

Whether you're ready to implement a FAST™ or just want to learn more about the program, one of our Strategy Advisors would be pleased to meet with you for an introductory session. Please contact us at solutions@harborclinical.com for more information.

See Case Studies on next page.

Case Study 1: Early phase FAST.

A small but growing Biotech was ready for clinical trials and needed an outsourcing solution.

Harbor Clinical Strategy Advisor developed a resourcing plan using the FAST model and presented it to the sponsor's Board of Directors. The subsequent decision was made to move forward with the FAST implementation below:

Role	Phase 1	
	Role	FTE
Medical/ Clinical Science	MD Consultant	0.5
Clinical Operations (ClinOps)	Director Level	0.5
Data Management	Lead DM	0.3
Biostatistics/Programming	Biostatistician (with programming)	0.25
Medical Writing	Medical Writer	0.25
Translational Medicine/Science	Consultant	0.25
Clinical Pharmacology	Consultant	0.5

Case Study 2: Biometrics FAST

A mid-sized Biotech with two clinical programs in late phase was struggling with CRO resourcing challenges and needed short term staff-augmentation support to finish key tasks. Harbor determined that the FAST approach would ensure high quality deliverables on time without impacting the study timeline.

The solution included:

- 1 Lead Data Manager to be assigned full-time for the first phase (approximately 3 months) and drop to 0.25 FTE thereafter.
- 1 Biostatistician available ad hoc to support sponsor Biostatistician.
- 1 Clinical Programmer 0.5 FTE assigned for 6 weeks to support TLF development and programming needs on both programs.

Case Study 3: Data Management Support

A small biotech company with four clinical programs needed Data Management support for key program milestone support. Up to this point DM oversight and support was provided by the Clinical team but given the pending lock timeline they sought DM functional support to support data quality.

The solution included:

- 4 Lead Data Managers: one for each program to work with the various vendors and the clinical team to appropriate oversight of the Data Collection and cleaning functions.
- 2 Data Managers – to support data management quality control of the work that the CRO and other vendors completed

The Lead Data Managers worked with the clinical team and with the Data Managers to design a Data Management oversight plan and a QC process for study data. Findings from this process were fed back to the clinical team and corresponding vendors to ensure the highest quality data for the program.