

Biostatistics & Programming Outsourcing

Boosting Sponsor Productivity with a Cytel “Extension Arm”

Challenge: Assemble a biostatistics and clinical programming team qualified to integrate with sponsor counterparts

Benefit: Increased clinical data programming, analyses and reporting at lower costs

Sponsor’s Challenge

Biostatistics and statistical programming personnel are hard-pressed to keep up in today’s “do more with less” biopharma industry environment.

Why? Typically, teams must support multiple development programs. They must also contend with growing product pipelines stemming from improved discovery efforts, increased early stage clinical successes, and programs inherited from mergers & acquisitions.

Even the most talented and efficient teams strain to keep pace with ever more clinical trials underway and on the horizon. Many feel they’re “victims of our own success.”

Is outsourcing a viable, sustainable option?

Can outside biostatisticians and programmers sufficiently boost the sponsor’s own stats and SAS programming output without compromising quality?

A European based large pharmaceutical company put that very question to Cytel. The key for this sponsor was sufficient demonstration of:

1. The remote personnel’s proficiency levels, and
2. The capacity to maintain accuracy even despite anticipated scaling.



Securing the project required three essential components:

1. Finding a team qualified to work with the sponsors personnel
2. Meeting sponsor standards, in adherence with FDA & EMA regulations
3. A lower cost solution than internal hiring

Cytel Team-Building & Integration with Internal Resources

Creating the External Biometrics Arm

The sponsor is increasingly launching later-stage studies, including pivotal trials in oncology and multiple sclerosis treatments.

To meet the rising technical and cost reduction demands, the sponsor investigates establishing a Cytel "extension arm" requiring:

- Productive advanced-degree statisticians and experienced SAS and R programmers, from Cytel's Europe and India locations
- Adherence to their own quality standards
- A smooth project start-up avoiding disruption to the internal team

Start-Up Plan

Matching overseas specialized work teams can be tricky business even for companies that outsource widely. Cytel's outsourced clinical services experience accounts for:

- Comprehensive needs specifications and definitions
- Fulfilling requisite skills based on needs specifications
- Better management of distributed work centers with automated e-reporting
- Regular communications between respective project managers

Outcomes

Cytel's statisticians and SAS/R programmers are now operating as an integrated extension of the sponsor's own team. Without compromising quality, they've measurably increased overall Biometrics productivity and decreased costs.

The Cytel Advantage

At Cytel, we use science and technology to change how clinical trials are designed and conducted because it improves success rates. Our software and services provide sponsors with crucial biostatistics and operations research knowledge. In fact, all 25 leading biopharmaceutical companies utilize Cytel to plan, implement and analyze their trials.

Automation Benefits

Once working with us, Cytel clients invariably value our ability to automate routine computational and process chores. For sponsors it means making the best use of their own internal talent.

Unexpected Benefits

Sponsors also come to value the independent peer validation from their Cytel counterparts. This sponsor's own biostats and data processes and practices continue to sharpen as a result of the ongoing collaboration.

Cytel Biometrics Extension Team

High quality.

Global productivity.

Lower cost.

