

# CLINICAL DATA YOUR WAY

**A BEST-FIT DATA MANAGEMENT  
SOLUTION FOR GENERICS**



# YOUR EDGE IN THE RACE TO FILE

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Generics companies race against the clock for the coveted “first to file” status, but data quality is under greater scrutiny than ever — particularly with CDISC requirements. Quartesian is your program’s turbo drive, providing best-in-class data management, biostatistics, statistical programming, and medical writing services, faster and more cost efficiently than you thought possible.

## QUARTESIAN QUICK HITS:

We’ve worked with **100+** pharmaceutical, biotechnology, and medical device companies

We support **400+** clinical trials over **2,000** sites across **20** countries

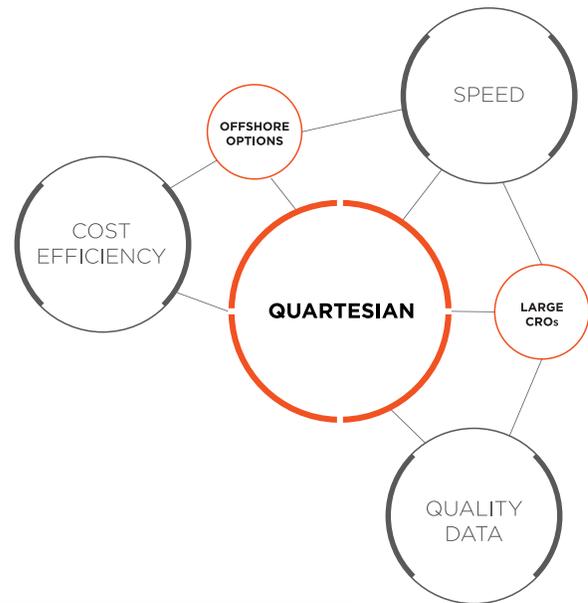
We enjoy **100%** repeat business and issue zero contentious change orders

## WHAT KEEPS OUR CLIENTS COMING BACK, INCLUDING 3 OF THE WORLD’S TOP 5 GENERICS COMPANIES?

We tailor our services to your specific needs, leaving out costly, unnecessary “extras” other CROs bundle into their offerings. With exhaustive experience in BA/BE and clinical endpoint studies — including CDISC datasets — we know the specific requirements facing the generics industry and offer high quality, low cost solutions at breakneck speed.

# THE QUARTESIAN DIFFERENCE

Full-service CROs provide quality and sometimes speed, but usually exceed budget with unneeded services and timeline-extending change orders. Low cost, offshore data solutions often sacrifice quality, increasing risk. **Only Quartesian has found the formula to provide all three, ensuring you're first to file.**



## HERE'S HOW WE DO IT

### ▸ CLINICAL DATA FOCUS

**Data is what we do** — and we do it full-time. We're the experts in gathering, organizing, analyzing, and formatting clinical data for regulatory submission. Our programmers leverage proprietary data technology, custom macros and automation, and our statistical programming platform to crunch huge data sets quickly and accurately.

### ▸ COMPLIANT DATA AND SYSTEMS, EXTENSIVE QA

Quartesian goes to great lengths to keep your clinical data safe with strict adherence to SOPs, ongoing quality audits, and extensive process for vetting and auditing vendor partners. Our comprehensive data management system is both user friendly and 21 CFR Part 11 compliant, for greater visibility and less risk.

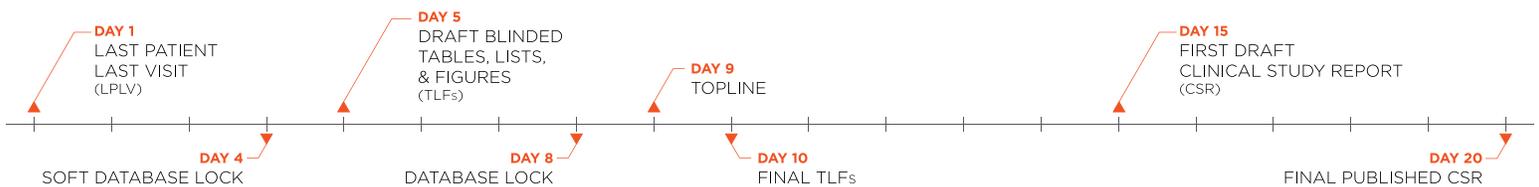
### ▸ BENEFITS OF A DOMESTIC/OFFSHORE SOLUTION, WITHOUT THE DRAWBACKS

Enjoy the perks of outsourcing without the capital expense of establishing your own sites or the risk of trusting your data to a subpar team. Our reputation overseas attracts top talent from around the globe, giving you the scalability and cost savings of a domestic/offshore solution while maintaining the highest levels of quality.

# THE PERFECT FIT FOR GENERICS

When filing, minutes – even seconds – count. Quartesian provides the same quality branded pharma programs demand, but with an aggressive first-to-file record. Enjoy access to our full-time QA department and 24/7 multinational support, at a fraction of the cost of competing solutions.

## A PROCESS TIMELINE TUNED FOR SPEED



## A PROVEN TRACK RECORD OF CDISC EXPERTISE



It's an all-too-common nightmare scenario: you've completed your program on time to be first to file, only to lose your place in line to a CDISC formatting error. A CDISC Gold Member, Quartesian has handled **thousands of CDISC datasets for generics**. We'll deploy a data capture system, build your study database, reviews and verify data, and provide it in a format ready for submission to regulatory authorities – along with a final analysis proving equivalence, sound trial design, and safety.

## BE FIRST TO FILE. CHOOSE QUARTESIAN.

Learn why **3 of the world's top 5 generics companies choose Quartesian.**

Email [info@quartesian.com](mailto:info@quartesian.com) or call 1.609.454.3312 to learn how our expert team of data scientists can give you Clinical Data Your Way – and an edge in the race to file.