CASE STUDY

# Four Months from Observations to Answers: WCG Avoca Addresses Mock Inspection Gaps to Ensure Biotech's Regulatory Review Readiness

## OVERVIEW

A small biotech specializing in Early Phase trials approached WCG Avoca for help tackling mock inspection observations surrounding a bioequivalence study. Issues included gaps in CRO oversight and standard operational procedures (SOPs) for good clinical practice (GCP) activities. In addition, they wanted to storyboard key aspects of the trial.

The client desired a partner with regulatory experience and knowledge of industry practices for GCP. They wanted a fit-for-purpose solution to meet small-biotech needs as well as global intel regarding CRO and sponsor operations. The client identified and selected WCG Avoca as a high-quality, collaborative solution provider with deep regulatory and industry expertise.

## THE CHALLENGE

This biotech was preparing for a marketing authorization application (MAA) with the European Medicines Agency (EMA). Having mock inspection observations in hand, they needed help identifying next steps to ensure regulatory review readiness.

The client chose to leverage WCG Avoca's expertise in working with CROs and sponsors to address gaps in their GCP activities while ensuring proper integration. This objective required the development of new, fit-for-purpose SOPs to facilitate compliant, best-practice operations.

Finally, a storyboard would highlight key aspects of the trial to showcase remediation and provide documentation of activities completed. It would also help the client tell their story to key stakeholders. The entire timeline was four months.

## SOLUTIONS

WCG Avoca formed a team of four experts and a project manager to collaborate with the client's team and then lead and implement project initiatives. Weekly communication with virtual sessions provided touchpoints

while marking progress. This strong working relationship was vital to achieving on-the-mark, rapid execution throughout the project.

We provided the client with services designed to meet their needs:

- **Mock inspection observation analysis and solution plan:** We conducted an in-depth, expert analysis of the client's mock inspection findings, assessing the results and completing root cause analysis to identify critical gaps. Our team delivered an action/solution plan to help the client close the observations identified and reach their desired state of inspection readiness.
- **Electronic Trial Master File (eTMF) audit:** The Trial Master File (paper or electronic) is a cornerstone of inspection readiness and a key focus of regulatory authorities. We reviewed the TMF contents against expected documents to assess gaps and provide insights on potential risk areas within the trial record. Our audit allowed the client to remediate eTMF issues in preparation for a smooth inspection process.
- **Development of SOPs and forms:** We developed the essential SOPs, including the associated forms and templates, to close gaps identified through the mock inspection observation analysis. These issues were associated with CRO oversight and required knowledge of best practices for sponsors' GCP activities. The new, fit-for-purpose SOPs facilitated regulatory compliance, inclusive of quality and efficiency in trial conduct.
- **Trial storyboarding services:** Our team formed a storyboard highlighting the complex issues surrounding the client's trial. We showcased remediation activities and compiled informal documentation of the peripheral activities associated with the identified issues and gaps to highlight essential evidence. The resulting storyboard was also designed to support this biotech in telling its trial story to stakeholders.

## LESSONS LEARNED

Clients such as this small biotech want fit-for-purpose solutions that can drill down to meet their unique needs; at the same time, they want the breadth of expertise offered by a global team well versed in regulatory requirements and industry standards. We provided flexible and comprehensive support – rather than off-the-shelf solutions – ensuring that the client received the services and achieved the results required.

Communication is key. We listened to the client's needs and closely collaborated with their team to meet stated objectives during this four-month period. Weekly interface kept the lines of communication open and marked progress. This approach created a strong working relationship between the WCG Avoca/client team – leading to effective execution and sustainable success.

Finally, clients appreciate flexibility, agility, and honest answers. This client had questions throughout the project. For those issues

brought to light through the mock inspection, they received specific solutions that would help them adopt industry standards for their practices. As the project unfolded, they had additional questions about processes and CRO/sponsor operations. They valued our team's agile response - helping them build their knowledge and confidence in anticipating and answering regulatory and stakeholder queries.

## OUTCOME

This biotech implemented our recommendations surrounding their Phase I bioequivalence trial, and they gave us high marks on our team's expertise and responsiveness throughout the process. We met all their goals along an aggressive four-month timeline - from observations to answers - and developed a close collaborative relationship as the client enhanced their regulatory review readiness.

### How can we help you improve quality as you strive to achieve meaningful clinical trial execution?

With WCG Avoca's expertise and fit-for-purpose solutions, you can discover the right services to meet your needs.

To learn more or to schedule an eTMF Inspection Readiness Assessment for your organization, contact:

Dawn.Auerbach@theavocagroup.com