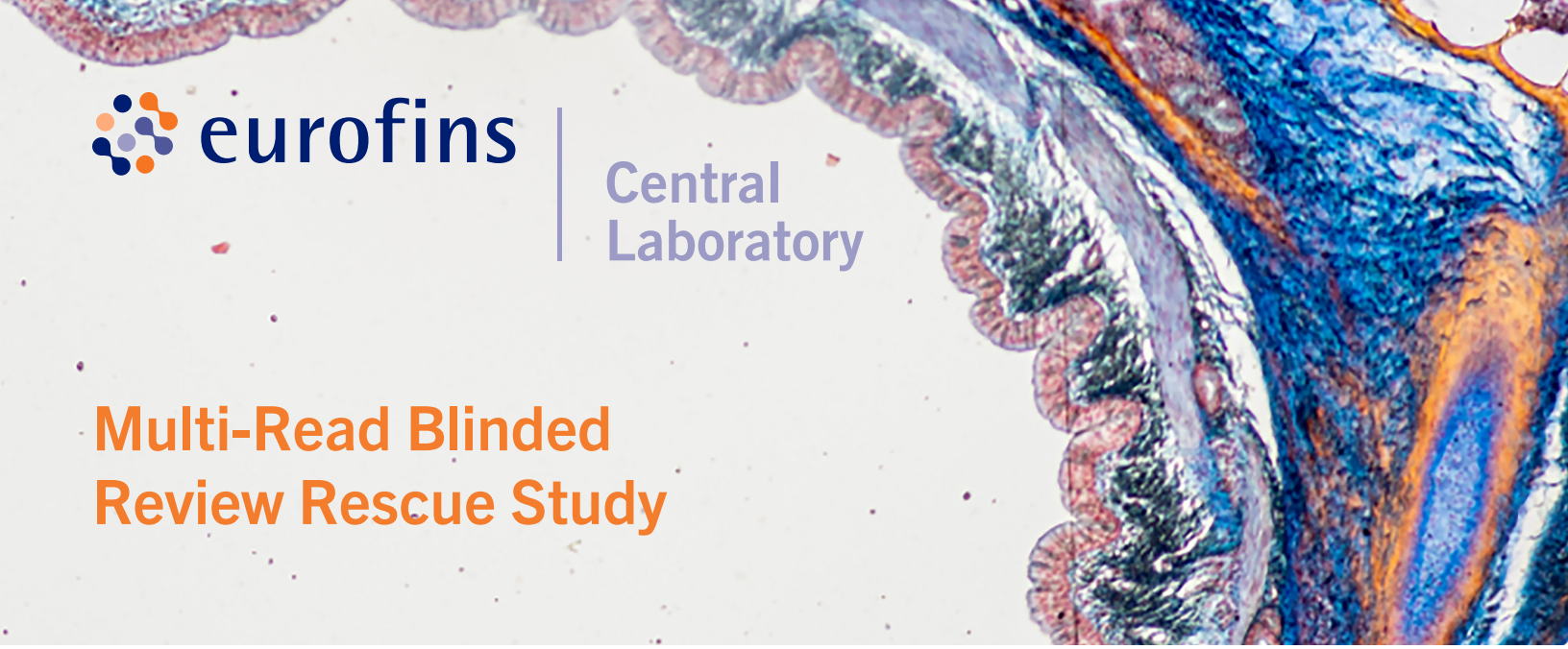

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Multi-Read Blinded Review Rescue Study

INTRODUCTION

This case study highlights a global Phase 3 clinical trial in the therapeutic area of endometrial health. Sponsored by a leading pharmaceutical company, the study involved 5,200 subjects and generated 10,400 independent reads, spanning multiple regions worldwide.

The Eurofins DCL Pathology group, part of Eurofins Central Laboratory, brought extensive experience in global clinical trial support, ensuring data integrity, regulatory compliance, and timely execution. This case highlights the challenges and solutions implemented to support such a large-scale study, offering insights into best practices for supporting high-volume central lab pathology in a dynamic and regulated environment.

CHALLENGE

The Eurofins DCL Pathology group was approached by the client concerning a large phase 3 trial already in progress with another vendor. The in-process phase 3 trial had several complex variables and tight timelines to meet study protocol:

- Results being provided by the current vendor did not meet the required turnaround time required by the client.
- The quality, consistency, and reliability of pathology was not deemed acceptable by the client.
- The database used lacked a standardized dictionary, using only free text form of data recording. Hence, data recorded by independent pathologists lacked uniformity:
  - Diagnostic reports were inconsistent in presentation to the sites.
  - Data needed by sponsor for submission was a challenge.
- There were previously read cases as well as new cases from the ongoing study to be managed.

APPLIED SOLUTION

While the Eurofins DCL Pathology group was able to onboard the rescue study within an expedited timeline, there were several key variables to address through expedited activities:

- A new database was built.
- A standardized diagnostic dictionary was established.
- All previously resulted cases were translated from paper reports to new database.
- New cases received as wet tissue were processed and assessed in a manner that created data uniformity for the client.
- Client was provided consistent turnaround time, despite facing a backlog of cases requiring re-interpretation.
- Client received all data needed for data lock had a successful FDA submission.

Multi-Read Blinded Review Rescue Study

RELEVANCE

The Eurofins DCL Pathology team strives to engage early in the study design phase, providing expert consultation to help ensure a well-structured plan and smooth trial execution. By identifying inefficiencies and harmonizing data collection processes from the outset, we contribute to improved operational outcomes and data quality.

- Histopathology involves intricate descriptions of tissue structures, changes, and disease states. A standardized dictionary ensures consistent terminology, facilitates accurate descriptions of disease states, harmonizes the interpretation of reports, and fosters clear communication among pathologists, clinical research teams, and sponsors.
- The overall clinical trial histopathology workflows, execution, and timelines were realigned and improved. This ensures that data returned to the client is captured using a consistent and standardized methodology, resulting in the highest quality for downstream analysis.
- The Eurofins DCL Pathology group supported critical clinical trial timelines and data integrity by re-interpreting a prior vendor's results. They also categorized these findings into a newly designed custom dictionary for the client.
- All new cases were processed and reported according to the established requirements, ensuring consistent and timely delivery of results.

CLIENT FEEDBACK

Sponsor was delighted by the entire engagement with Eurofins DCL Pathology. As a result, the client has used Eurofins DCL Pathology for their ongoing and new studies.

RECAP - A CONSULTATIVE APPROACH

Anatomic pathology is often a small component of an overall clinical trial, yet it presents a highly complex problem set in terms of study design yet highly complex area of clinical trial design. The Eurofins DCL Pathology group provided re-interpretation of the prior vendors results and categorization into the newly designed custom dictionary for the client. A consultative approach to central lab pathology is the key advantage of the Eurofins DCL Pathology offering.

Decades of clinical trials and diagnostic experience are leveraged to not only meet the needs of each trial, but in many instances to improve study design and execution through creative solution offerings, which include:

- Customization and codification of diagnostic dictionaries on a per-study basis, removing the ambiguity in final data analysis so often present due to standard pathology reporting.
- Proper tissue logistics and process flow, treating each irreplaceable sample with the utmost care.
- In-depth clinical protocol review and recommendations on appropriate assays and technologies in the context of each protocol, including innovative molecular pathology assays.
- Excellence in histopathology processing, embedding, and microtomy, resulting in the most effective microscopic visualization possible.

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