



Versiti Clinical Trial Services **An Integrated Approach** *to Support a 510(k) Submission*

Executive Summary

Versiti, a leader in clinical trial services and starting biomaterials for research, partnered with a medical technology and pharmaceutical company to support a 510(k) submission for a medical device under a critical time crunch. Versiti's integrated clinical and scientific expertise in transfusion medicine and hematology, combined with its comprehensive clinical trial services, provided an all-in-one service package that drastically reduced project time and logistical complexity and enabled the client to meet an 8-week window for FDA submission.

Consultative Approach

Versiti held multidisciplinary meetings with the client to understand the project scope in order to design the best solution. Having a centralized partner providing project management and a comprehensive suite of specialty services allowed the client to complete their project sooner than outsourcing each element individually. Through these conversations, it was determined the client needed:

- Assay development and execution
- Central laboratory services
- Biomaterials for research

Versiti shared its suite of capabilities to meet the project's scope and build a trustworthy partnership with the client. We were able to learn and execute the client's device process quickly.

Specialty Clinical Trial Services

The Versiti team built a customized testing solution for the client. The following services were provided:

- Project management, including leading study meetings
- Study and data management, including comprehensive and customized study report
- Development and execution of new tests, including procuring specific reagents and developing unique methodologies for hemoglobin and hematocrit testing
- Comprehensive testing services throughout the study, including hematology and coagulation testing
- Shipping and logistics

Biomaterials for Research

Versiti is the largest independent blood bank in the upper Midwest. The provision of products for this project did not impact Versiti's ability to serve the transfusion medicine needs of the communities we serve. To support this client, we prepared and provided the following products to validate testing, which required a specialized process that involved testing products from specific collection time points:

- Fresh frozen plasma
- Packed red blood cells
- Platelets
- Whole blood

Impact and Outcomes

Versiti's ability to provide assay development, customized testing, and blood products for research, in the correct regulatory environment, led to significant time savings for the client. The client did not have to contract with multiple providers because of the integrated service efficiencies Versiti could provide, which was critical given the deadline for FDA submission. The entire project from testing to completion was done in six weeks.

This case example demonstrates how Versiti consults with partners to identify custom solutions tailored to each unique project's demands.

About Versiti

Versiti provides expert support for a diverse range of clinical trial needs. Our comprehensive approach includes logistics, assay and biomarker development, IRB services, central laboratory services, blood products for research, and more. Our depth of expertise across the spectrum of blood health and clinical trials ensures nimble, high-quality, efficient and reliable results. We are your partner throughout every stage of your clinical or academic research.

To learn more about Versiti's clinical trial services and biomaterials for research, visit versiticlinicaltrials.org, or contact us at clinicaltrials@versiti.org.



For more information about our services, contact: Clinicaltrials@versiti.org