

Prospective Study

Rapid serum procurement for a vaccine trial

Study of 300 adults immunized with a competitor's product completed within four months



Challenge

Blood draws from subjects in the early phase (e.g., 1–6 months) after immunization provide essential information on the immune response; however, prospectively recruiting study participants can be costly and logistically demanding.

Client: Clinical immunology director at a multinational biopharmaceutical company

Solution



Study enrollment:
300 Serum samples 3 clinical sites



Laboratory:
Infectious disease testing and storage



Inclusion criteria:
Adults who have had a confirmed immunization with a competitor's vaccine within the past 1–6 months.



Metadata:

- Age & demographics
- Date of immunization
- Vaccine status
- Medical conditions



Exclusion criteria:
Known or suspected immunodeficiency or receiving immunosuppressive therapy



**Completed in
4 months**

Results

Rapid progress in sample collection encouraged the client to expand the study to 300 serum samples. Overall, the study was completed in less than 4 months across 3 sites.

Based on Boca's scientific expertise and fast turnaround, the study is currently undergoing expansion to recall up to 20 specific subjects for repeat donations.

Summary

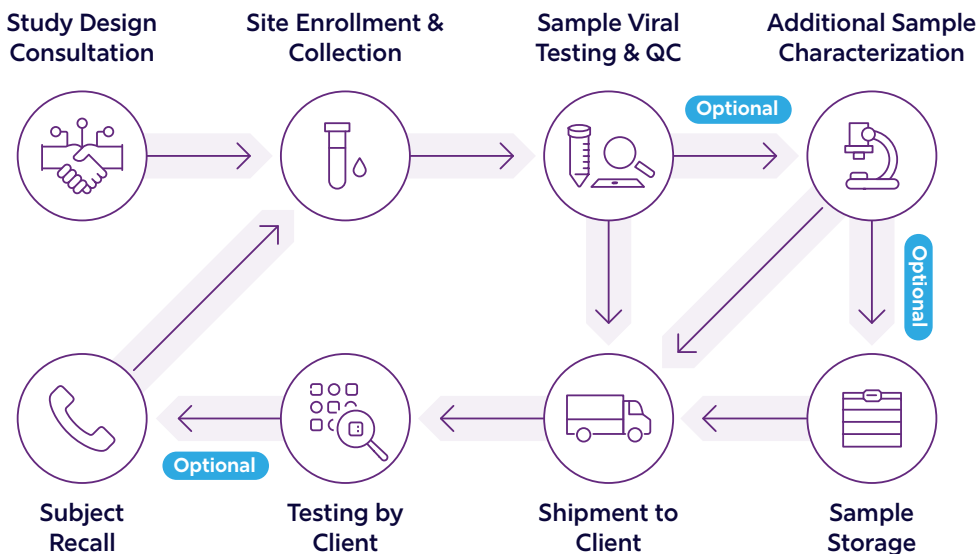
The six-month window after immunization can provide valuable insights into circulating cytokines, interferons, and other immune response biomarkers (Grippin et al., 2025).

To complement the clinical development of a novel immunization, a global biopharmaceutical company engaged Boca Bio to prospectively collect 200 serum samples from adults who had received a competitor's vaccine within 1–6 months before collection. Subject metadata, including demographics and vaccine status, along with the exclusion of donors with potential immunosuppression, increased the likelihood of study success.

Serum samples were collected at three sites across the US and stored at Boca's CLIA and CAP-certified biorepository in Florida (see Figure). The study progressed so quickly that the client requested an additional 100 samples, increasing the total to 300 serum specimens.

The project is now expanding to include a longitudinal component, recalling up to 20 specific subjects for repeat collections.

Characterization of these specimens will ultimately guide the clinical development of the client's novel vaccine, including benchmarking immune biomarker responses and identifying potential product differentiators at the molecular level.



Typical study workflow at Boca Biolistics with optional steps labeled. See our [central laboratory analytical and testing solutions](#) and [biostorage options](#) for more information.

Ensuring data privacy

Boca Bio uses a 21 CFR part 11-compliant electronic data capture (EDC) system to collect only relevant data, including automatic redaction of all protected health information (PHI) in accordance with HIPAA regulations. Our commitment to data privacy and quality management is further upheld by our ISO 13485:2016 certification, which ensures that all processes meet rigorous international standards for data integrity and security.

Reference

Grippin, A.J. et al. (2025) "SARS-CoV-2 mRNA vaccines sensitize tumours to immune checkpoint blockade." *Nature*, pp. 1–10. Available at: <https://doi.org/10.1038/S41586-025-09655-Y>.