



› CASE STUDY

Should an Oncology Study Expand Into Europe?

A Quick Feasibility Study of Sites Throughout Europe

Background

A clinical stage biotechnology firm requested that Veristat help them build a feasibility project to assess whether it was feasible and worthwhile to expand their current study into European sites. The ongoing early-phase project in patients with advanced solid tumors was being conducted at sites in the United States and Canada.

The project had some very specific technology requirements for the sites and part of the assessment was to determine if that technology was available at sites in Europe. Veristat began the feasibility project with a goal of delivering the final feasibility report in under six weeks.

Goal

A biotechnology firm focused on using precision medicine to treat cancers came to Veristat to complete a feasibility assessment to find sites in Europe that could be part of a Phase IB expansion study. The sponsor was concerned about expanding into Europe because the sites would be required to have a specialized imaging technology onsite to assess the biomarker status identified by a companion diagnostic imaging agent.

Solution

Veristat's medical monitor set up a two-stage feasibility questionnaire that was distributed to its existing network of clinical trial sites in 14 countries that Veristat identified throughout Europe. Our medical monitor performed a detailed analysis of each site's capability and capacity to conduct the study, enroll the right patients and provide the imaging technology required for the study.



STUDY DEMOGRAPHICS

INDICATION

- Non-Small Cell Lung Cancer (NSCLC)

STUDY PHASE

- Feasibility for Phase IB Expansion Outside of US

SITES

- 48 Evaluated

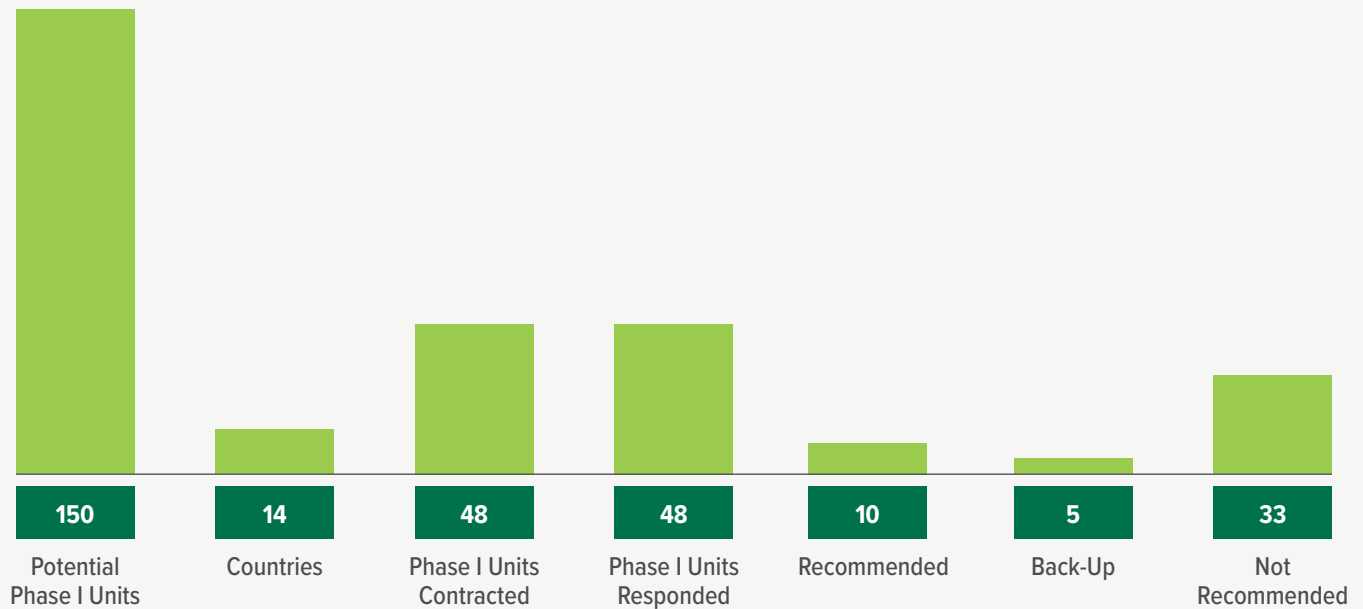
REGIONS

- 14 Countries: Austria, Belgium, Czech Republic, Denmark, France, Germany, Greece, Hungary, Italy, Netherlands, Norway, Poland, Spain & United Kingdom

SERVICES PROVIDED

- Site Feasibility Assessment

Feasibility Phase I NSCLC



Results

Veristat completed and delivered a detailed feasibility report to the sponsor within 5 weeks with recommendations on the number and location of sites that could deliver the right patients and provide the specialized technology imaging test. Veristat recommended that they move forward with the study in Spain and the United Kingdom where we identified 10 sites with a recruitment potential of 45 patients within 6 months. The sponsor moved forward with Veristat's recommendation and completed their Phase IB expansion study in Europe.

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To learn more about Veristat and how we can help you achieve success with your trial or development program and regulatory submission, reach out to us today.

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