An Inteliquet Biopharma Case Study

Advanced insights driving improved protocol feasibility and design

inteliquet

inteliquet.com

Executive summary

Advanced insights driving improved protocol feasibility and design.

The Sponsor:

Emerging oncology research and development organization who was looking to conduct a clinical trial in the United States.

The Challenge:

To conduct a clinical trial in patients with follicular lymphoma (FL) whose disease state had progressed after at least three lines of therapy. The sponsor was concerned about availability of patients at this stage of treatment and the impact of laboratory values on patient eligibility.

The Solution:

A feasibility analysis based on the data available for FL patients in the Inteliquet consortium that matched the primary inclusion/exclusion criteria provided by the sponsor.

The Results:

The Inteliquet analysis was able to improve the success of the FL trial by accurately providing the sponsor with a forecast of patient availability by US geographic region based on the past several years as well as an assessment of different laboratory limits, including how the variability of each limit affected the probable availability of patients for the clinical trial.

The challenge

Follicular lymphoma (FL) is a particularly difficult cancer for which to conduct a clinical trial.

- FL is typically a slow-growing or indolent form of non-Hodgkin lymphoma (NHL) that arises from B-lymphocytes, making it a B-cell lymphoma.
- In addition to standard treatment options, if patients show no or very few symptoms, physicians may recommend active surveillance. This can limit the availability of patients who are considered for treatment.
- Competition within the U.S. for these patients is high, as there are more than 100 studies currently open and enrolling patients with follicular lymphoma.
- Patients had to have received at least three lines of previous therapy to be eligible for the study.

The solution

A feasibility analysis based on data available for FL patients in the Inteliquet consortium that matched the trial primary inclusion/ exclusion criteria.

- Extracted data for Follicular Lymphoma patients within the Inteliquet Consortium.
- Analysis of first lab result after patient would have been available for the trial.
- Analysis of best lab result during patient's available window for the trial.
- Forecast patient availability per year across geographic regions.

The results

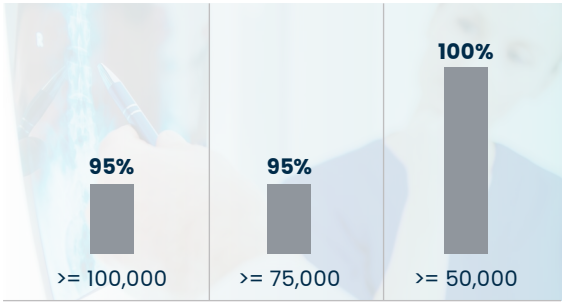
Protocol is open for enrollment—providing a new clinical trial option for patients with Follicular Lymphoma.

Successful feasibility of FL trials using forecast of patient availability by US geographic region and assessment of different laboratory limits, including how the variability of each limit affects the probable availability of patients led to the finalization of a protocol that is now open for enrollment.

U.S. Region

	Midwest	Northeast	South	West
2012	4	3	9	23
2013	30	0	14	54
2014	13	0	14	17
2015	8	7	21	43
2016	0	4	0	15
2017	0	4	0	10

Proportion of available patients based on platelet count



Correlation of laboratory tests

Pairwise correlation (same test day) of quantitative labs: insight into how tweaking one lab result affects others.

	ALT	AST	Biliru	CrCl	Hemogl	Neutro	Platel
ALT	1.0000						
AST	0.7933	1.0000					
Biliru	0.1618	0.1007	1.0000				
CrCl	0.1599	0.0441	-0.0322	1.0000			
Hemogl	0.1409	-0.0260	0.0602	0.1483	1.0000		
Neutro	0.0308	0.0508	-0.0058	-0.0462	0.0189	1.0000	
Platel	-0.0402	-0.0350	-0.1414	0.0924	0.1304	0.4379	1.0000

inteliquet

Contact us

info@inteliquet.com • inteliquet.com