

OPTIMIZING CLINICAL TRIAL DESIGN & SITE ENROLLMENT

Client sought to optimize their clinical trial design, site selection, patient enrollment, and identify suitable KOL partners

SITUATIONAL ANALYSIS

- Client, a mid-sized pharma, was entering Phase 2 clinical trials for a drug targeting DLBCL
- The client had limited prior experience clinically developing an asset in the oncology space
- Given the large number of competitors pursuing DLBCL indications, the client required help with:
 - Designing clinical trial (sample size, endpoints, inclusion / exclusion criteria, geography)
 - Identifying all potential sites in the US and EU
 - Stratifying sites based on patient subtypes in DLBCL (e.g., CD20+, CD19+, MYC+)
 - Prioritizing sites based on recruitable populations and competition at sites for patients
 - Identifying top and emerging KOLs

SOLUTION

1. Clinical Trial Comparator (CTC) Dashboard

To design the client's clinical trial, Innoplexus leveraged its CAAV™ technology to continually:

- Assess all past and ongoing clinical trial in DLBCL, as well as the drugs' regulatory approval

2. Site Optimization & Enrollment (SOE) Dashboard

To identify clinical trial sites for DLBCL, Innoplexus created a custom dashboard which identified and prioritized sites based on:

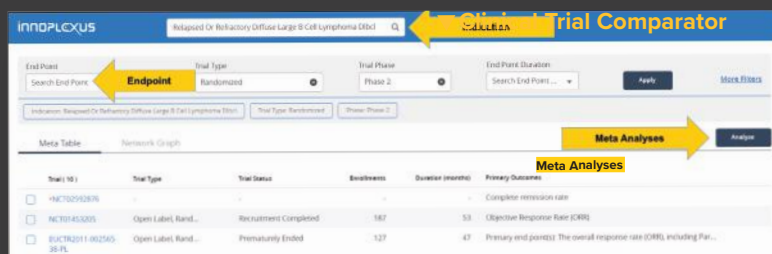
- Geography
- Disease epidemiology
- Site capacity
- Past and current competitor clinical trials
- Patient histological data
- 3rd-party data / internal performance data

A Clinical Trial Comparator dashboard was developed to enable the client to rapidly compare past and current trials in DLBCL and similar indications across a number of parameters

METRICS EVALUATED

- Trial**
 - Trial Sponsor
 - Trial Start / End date
 - Trial Duration
 - Trial Site Locations
 - Investigators
- Intervention**
 - Phase of Drug
 - Indication
 - Mechanism of Action
 - Route of Administration
 - Comparator Drugs
 - Primary Endpoint
 - Secondary Endpoint
 - Inclusion / Exclusion Criteria
- Reg.**
 - Regulatory Approval Date
 - HTA Decision Date

Non-exhaustive list



INNOPLEXUS TECH OVERVIEW

- Innoplexus continually crawls the web, identifying and updating dashboard information in real-time, ensuring clinical trial design decisions are based on the latest information

BENEFITS

- By connecting these data points, Innoplexus determined an optimal trial design, which is most likely to achieve regulatory & commercial success
- Innoplexus's technology automated meta analysis and provided actionable insights, significantly reducing time needed for analysis

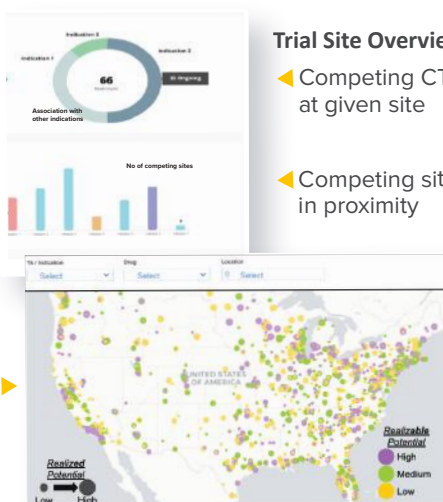
Sites were identified and prioritized based on past involvement in DLBCL with similar patient segmentation, site geography, competitor clinical trials, and recruitable patient populations

Parameters for Evaluating Sites

- Geography
- Disease epidemiology
- Site capacity
- Past and current competitor clinical trials
- Patient histological data (where available)
- Third-party data / internal performance data

Non-exhaustive list

Heat Map of CT Sites & their Potentials



Trial Site Overview

- Competing CTs at given site
- Competing sites in proximity

INNOPLEXUS TECHNOLOGY OVERVIEW

- Innoplexus developed customizable:
 - Visualizations to enable rapid evaluations of sites
 - Filters to allow for client-specific weighting of metrics for success
 - Integration of clients enterprise and third-party data to provide more robust insights

BENEFITS

- Innoplexus developed custom dashboards that evaluated and prioritized individual sites, and generated heat maps based on "realizable" potential, which was based on predefined parameters
- The numerous parameters considered enabled the client to quickly triangulate optimal sites

To improve the likelihood of regulatory approval and commercial success, Innoplexus leveraged publicly available patient histological data to estimate prevalence based on patient subtypes

Actual Trial Site Data with Publicly Available Patient Histological Data

TRIAL SITES	HISTOLOGICAL SEGMENTATION OF PATIENTS ENROLLED FOR DLBCL TRIAL
<ul style="list-style-type: none"> National Institutes of Health Clinical Center, Bethesda, MD, US Illinois Cancer Specialists, Niles, IL, US Mayo Clinic, Rochester, MN, US Northwest Cancer Specialists, Pharmaceuticals, Vancouver, WA, US Northwestern University, Chicago, IL, US 	<ul style="list-style-type: none"> CD20+, CD19+, CD30+, HIV+, ID10+ CD20+ MYC and BCL2 rearrangements, denovo GCB or non-GCB DLBCL, CD20+, FL CD20+, including Grade 3b FL, CD70+ MYC+, CD20+



INNOPLEXUS TECH OVERVIEW

- Vast ontology allows our solutions to identify and capture patient endotypes and link them to sites
- Ability to pull in additional laboratory results or clinical records from client enterprise data or third-party assets



BENEFITS

- Leveraging the available histological data at sites, Innoplexus provided a more targeted approach to site selection (potentially faster enrollment)

To identify potential KOL partners for the client, Innoplexus's KOL Discovery Platform assessed, segmented, and prioritized KOLs by asset classification, experience and connections



INNOPLEXUS TECH OVERVIEW

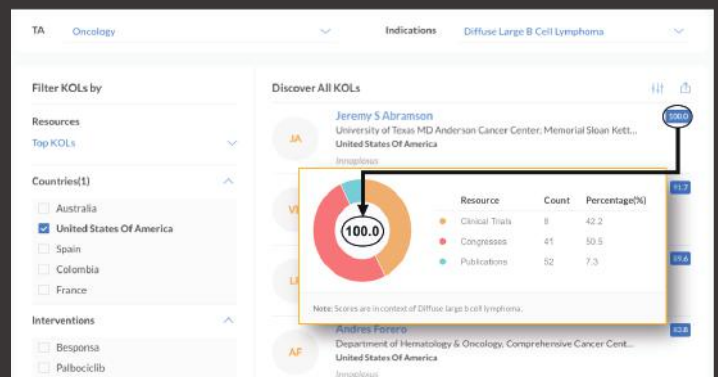
- Innoplexus's KOL Discovery Platform enables users to:
 - View KOLs involvement by all asset classification publications, Clinical Trials, congresses, HTA, guidelines etc.
 - Segment KOLs into four buckets based on their activities (thought leader, speaker, scientific, commercial)
 - Identify emerging vs. top KOLs



BENEFITS

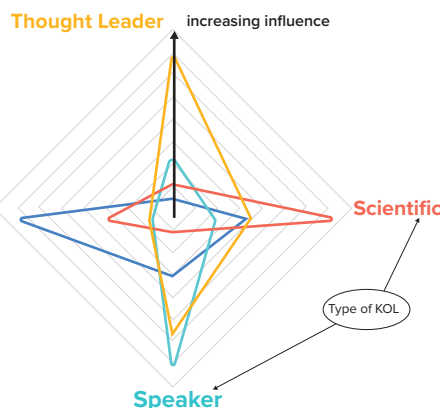
- Innoplexus provided the client with a dashboard containing:
 - A breakdown of trial naïve vs. experienced KOLs, by KOL type
 - Connections between principal investigators (KOL network map)
 - Customizable KOL scoring (varying weighting of metrics), which enabled faster and more data-driven site selection and access to optimal KOLs

Key Opinion Leader Discovery Platform



The client was able to understand the strengths of individual KOLs based on an influence area map, developed from information housed in Innoplexus's data ocean

Visualization Example Influence Area Map



Thought Leaders (Advocates)

- Public speakers (e.g. awareness drivers, social media, press, TV)
- Presidents of large groups (e.g. Medical Associations, PAGs, Charities, Foundations)
- Strong relations with regulatory bodies (e.g. President, Chair, Advisor, PI)
- Strong relations with HTAs (e.g. Evaluator, President, Advisor, Researcher)

Speakers (Topic Expert Recognition)

- Multidisciplinary group leader, generates meetings with peers & interdisciplinary areas
- Industry association as disease and therapeutic area expert
- Plenary/special events speaker in large global forums (e.g. ASCO, ESMO)

Scientific (Researchers)

- Published in major journals, with and without industry association
- Peer recognized as the area expert, e.g., researcher in globally recognized center
- Produces global guidelines, treatment recommendations with major scientific societies
- Works as a Principal Investigator for major clinical trial in the disease area*

Commercial (Business Oriented)

- Owner or partner in a private practice
- Strongly related to distributors and payers and heavily involved with pharma industry
- Directly involved in drug purchase and approval processes
- High prescription rates in the disease area*