TA Scan Trial Feasibility Use Case



OTA Scan

Clinical Intelligence Solutions

Clinical trial feasibility is a highly complex process, where teams need to combine operational expertise and experience with the ever-growing broad range of internal and external data sources. TA Scan's Trial Feasibility Flex module simplifies this process, adding strategic and operational value. The highly flexible solution allows the incorporation of internal insights on top of high-quality external data, to generate precise predictive enrollment scenarios for streamlined and impactful trial planning.

For a phase 3 study for non-small cell lung cancer patients with EGFR mutations, the sponsor wanted an evidence-based approach during feasibility assessment. In this use case TA Scan's built-in advanced analytics turned high-quality data and internal insights into actionable insights:

- Country selection strategy, based on analogous historical trials, current competitive landscape, and site and PI experience and availability
- Strategic feasibility assessment to assess whether timelines are realistic, to identify sites with sufficient capacity without competing trials

Study profile

- Indication
 Non-Small Cell Lung Cancer
- Subpopulation EGFR mutation
- Phase 3
- Region Multicenter, global - TBD
- Enrollment target 500
- Recruitment period 24 months

Country Selection



TA Scan identified 2 812 non-small cell lung cancer that focus on patients with EGFR mutations. 198 of these trials are commercially sponsored, phase 3 trials with a start date the past 10 years.

TA Scan's **country analytics report** was used to determine the optimal mix of countries based on:

- Analogous historical trials
- Competing trials
- Sites with relevant experience
- Experienced investigators

Using TA Scan, an analysis was performed of the number of relevant studies involving this specific patient subpopulation, using key criteria such as disease area, subpopulation, trial phase, sponsor type, study start date, and geographical region. Selecting trials with a similar design and patient population was crucial to ensure meaningful insights were extracted.

By leveraging TA Scan's country analytics report, factors such as prior experience and competition for patients were combined with internal insights such as business strategy, and local presence. Based on this, 10 countries were identified for further in-depth analysis using TA Scan's Trial Feasibility Flex module to generate predictive enrollment scenarios.



Global distribution of top tiered sites with experience in phase 3 non-small cell lung cancer with EGFR mutation trials.

Trial Feasibility Assessment

Incorporating Internal Insights for Precision

TA Scan's **Trial Feasibility Flex** module integrates high-quality data with customizable manual inputs, enabling precise enrollment projections tailored to your trial design. Through its simulation module, users can assess the impact of a wide range of variables – such as country selection, patient distribution at the country level, regulatory delay, anticipated recruitment rate, and other trial parameters – on clinical outcomes. TA Scan's Trial Feasibility Flex provides the actionable insights needed to optimize country and site selection, supporting confident and efficient trial planning.

Timelines Preferred site list Site drop out Benchmark data Regulatory lag

Trial Feasibility Flex Insights

Using TA Scan's extensive enrollment and trial timing data with actual enrollment rates, the TA Scan's Trial Feasibility Flex module provided the clinical trial outcome enrollment scenario for the phase 3 non-small cell lung cancer with EGFR mutations study enrolling 500 patients in 24 months in the 10 selected countries. On top of the predictive enrollment projections, TA Scan Trial Feasibility Flex report provided valuable strategic insights on country-level timelines, the competitive trial landscape, and site capacity.



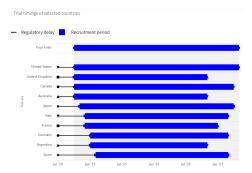
Predictive Enrollment Projections

- Build enrollment scenarios with TA Scan's global trial intelligence, enhanced by user insights, for accurate and tailored projections.
- Set realistic enrollment expectations to support clinical trial planning and budgeting
- Drive predictability in timelines and avoid costly protocol amendments

Using the reference list of trials, TA Scan's bespoke Monte Carlo simulation projected a 7-month extension of the recruitment period and a deficit of 13 patients.

Trial Timings per Country

Visualize projected **country-level timelines**, including regulatory delays and site start-up timelines



The trial timings of selected countries showed the longest recruitment period in the United States, despite the short country start-up timeline.

Competing Trial Landscape

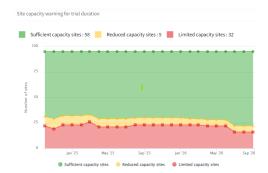
Understand the **global competition for patients**, for both ongoing and planned trials



Over 30 ongoing ph3 trials were competing for the same patient population globally, of which 15 were actively recruiting.

Site Capacity Calculations

Prioritize the preferred, experienced sites based on a site's **capacity to recruit**



The site capacity calculation identified 37 sites with reduced or limited capacity in the coming 18 months. Snapshot shows analysis for Canada.

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Learn more about Anju's Data Science Solutions and Services. Scan the QR code.