



Study Startup Around the World

A quarterly analytical discussion

ChromoReport



Introduction

Complexity in clinical trials continues to grow—a confluence of globalization, outsourcing, protocol complexities and ever-increasing regulatory mandates. Adding to this dilemma is the low approval rate of investigational drugs and growing development costs. Despite the nuances between therapeutic areas, the preliminary step of all clinical trials is study startup, which is widely recognized as a costly and perpetual bottleneck.

Study startup is a complex business involving country selection, pre-study visits, site selection and initiation, regulatory document submission, budget and contract negotiations, patient recruitment initiatives, and enrolling the first patient.



Study startup is a journey, and as with any journey, there are many ways to approach it. The first question is, how are you going to navigate? Fifteen years ago, you may have had no choice but to rely on paper-based maps and transcribed directions, which might have turned out to be obsolete or erroneous. But now, you have web-based maps that are always up-to-date and supplemented with satellite images and crowd-sourced, real-time information. What if you had this kind of navigation for study startup?

Imagine traveling through multiple countries, having to navigate routes with different road rules and signs in foreign languages, not aware of potential upcoming traffic bottlenecks or alternative routes.

Determining the start-to-finish (guided directions), optimal route and estimated arrival time is dependent on utilizing a framework that not only guides sponsors and CROs to compliance using workflows consistent with organizational standards and country-specific regulations, but also provides advanced predictive analytics by leveraging machine-learning capabilities to guide clinical research staff in their daily activities.

Study Startup Map

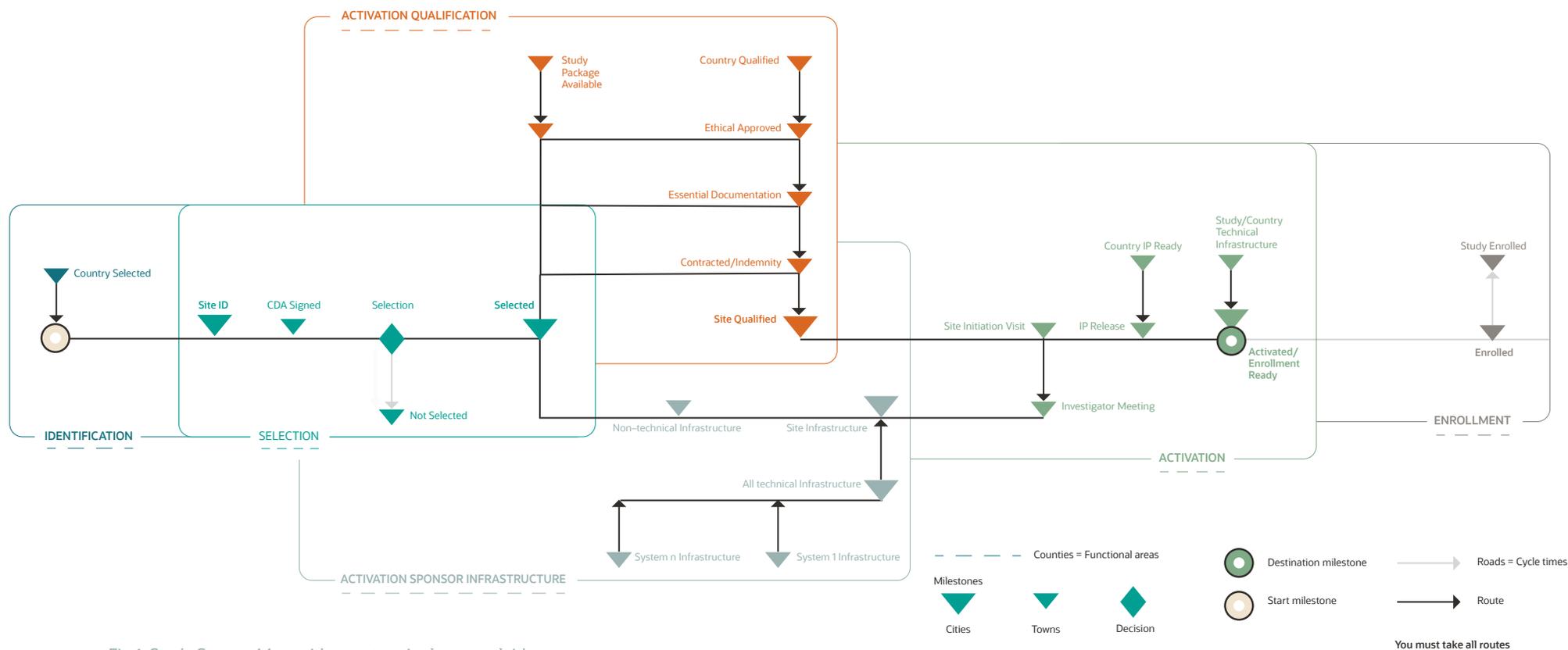


Fig 1. Study Startup Map, with map terminology overlaid

This framework, or Study Startup Map (Fig 1.) provides a common view, irrespective of specific country/regulatory requirements. It looks at one aspect cycle times but could easily be extended to include prediction for quality, enrollment, costs, resources and satisfaction/NPS aspects, as well as, being extensible to include country, study and program levels.



The Journey to Study Startup Optimization

As the industry leader in study startup, Oracle Health Sciences is well positioned to standardize across multiple data sets, to provide a single view of the real-world metrics and cycle times for study startup and is working with other industry groups (e.g., Metrics Champion Consortium, TMF Reference Model, etc.) to define study startup milestones.

Oracle Health Sciences' in-depth experience and comprehensive wealth of standardized metrics ensures that organizations can benefit immediately from predictive capabilities.



Navigating Milestones

Based on comprehensive standardized study startup metrics from machine learning on over 140,000 sites from sponsors/CROs studies utilizing the Oracle Health Sciences Activate Cloud Service, we have identified the following leading indicators (Fig 2.) as important to the prediction of the *Site Qualified* milestone date.

For example, using these leading indicators for a Phase III, Oncology, multi-country study, a USA-based site is predicated to have a cycle time of 101 days from *Site Package Sent to Site to Site Qualified*. If the site study package was sent to the site on November 22, we would predict that the site would be qualified for activation by March 2.

How does this look for Site Qualification planning?

What determines when will we get there? Predictive analytics based on machine learning.

Leading indicators

Number of countries	15
Sites in study	141
Sites in country	29
Start month	11
PI in study counts	12
Therapeutic area	Oncology
Phase	III
Country code	USA
IRB/EC type	Central

Prediction

Duration (days)	101
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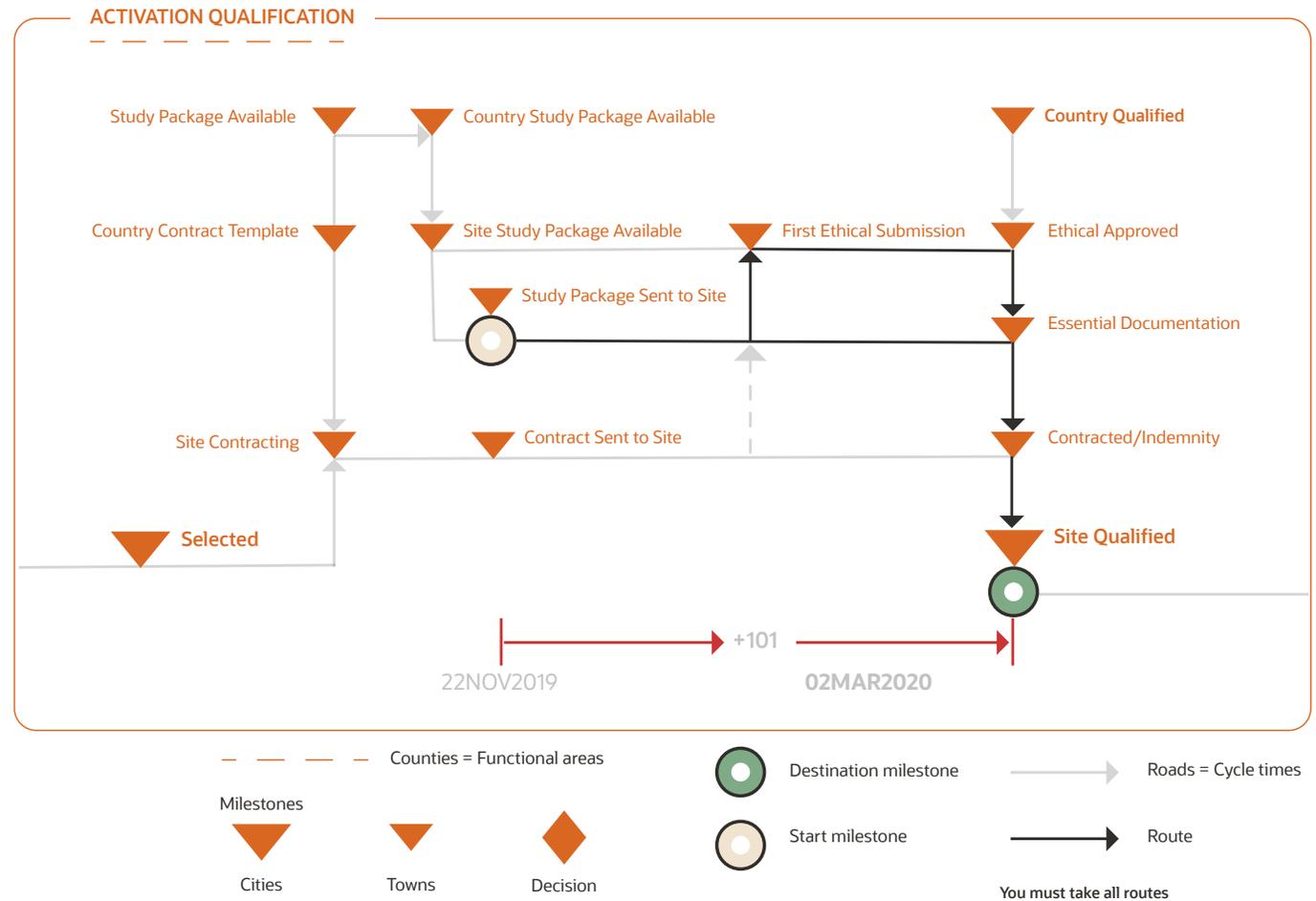


Fig 2. Activation Qualification component of Study Startup Map

In Summary

Purpose-built study startup systems that capture standardized metrics and utilize advances in data analytics, visualizations, and prediction have now become an integral component of decision support systems. These systems aid compliance and empower clinical research teams in improved risk management and proactive planning practices, providing the best map for your study startup journey.

Predictive analytics...

- Are a powerful tool for proactive planning of clinical trials and RFP bidding for CROs, which organizations can immediately benefit from with direct implications on timelines and associated costs.
- Require comprehensive standardized metrics and in-depth experience to ascertain leading indicators for associated aspect/milestone predictions.
- Based on a robust framework and machine learning, can allow prediction for quality, enrollment, costs, resources and satisfaction/NPS aspects, as well as, being extensible to include country, study and program levels.



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