The TIME Trial® Network facilitates rapid clinical trial activation, patient screening, and enrollment in molecularly targeted trials

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INTRODUCTION

Clinical trials with molecular targets present unique barriers to patients, trial sites, and sponsors. Such barriers can limit access for patients, slow the pace of trial enrollment, and delay the development of new therapeutic options.

The TIME Trial Program was designed to activate clinical trials rapidly on behalf of patients. This just-in-time rapid activation program utilizes proprietary pre-screening technology and a nationwide network of research sites and pharmaceutical sponsors to identify and enroll specific patient populations.

METHODS

Tempus Labs has partnered with experienced research sites and pharmaceutical companies with molecularly targeted clinical trials to create the TIME Trial Network. The study portfolio includes industry sponsored phase I-III clinical trials across solid tumors and hematological malignancies, targeting actionable mutations. This network was established to ensure rapid just-in-time (JIT) activation of trials by streamlining start-up activities.

Figure 1. TIME Network Requirements

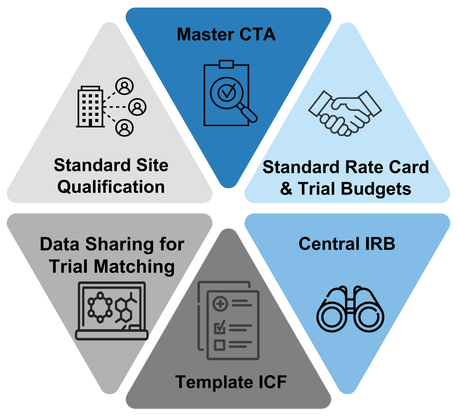

Figure 1. TIME Trial Network site requirements to streamline start-up activities and enable JIT activation of trials.

SUMMARY

TIME Trial Program enables **rapid site clinical trial activation** in an average of **<9 days**.

The average time from **activation to patient consent** was **4 days**, with 50% of patients consenting within 1 day.

The timeline from **patient consent to first dose** was completed in an average of **7.2 days**.

RESULTS

Table 1. Activation Activities and Timelines

Timeline	Minimum	Average
IRB Submission to Approval	Same Day	2.4 Days
Activation Initiated to Fully Executed Contract	2 Days	5 Days
Activation Initiated to Activation Completed	2 Days	8.5 Days
Site Activated to Patient Consented	Same Day	4 Days
Patient Consent to First Dose	Same Day	7.2 Days

Timelines are represented in business days.

Table 1. Activation data was analyzed over an 8-month period across 15 TIME Sites. Rapid activation initiates upon receipt of an activation form from a site partner. "Site Activated" describes a site that has fulfilled all regulatory documentation, contracting, and has sponsor approval to screen and enroll patients.

Figure 2. TIME Trial Network Heat Map in the United States

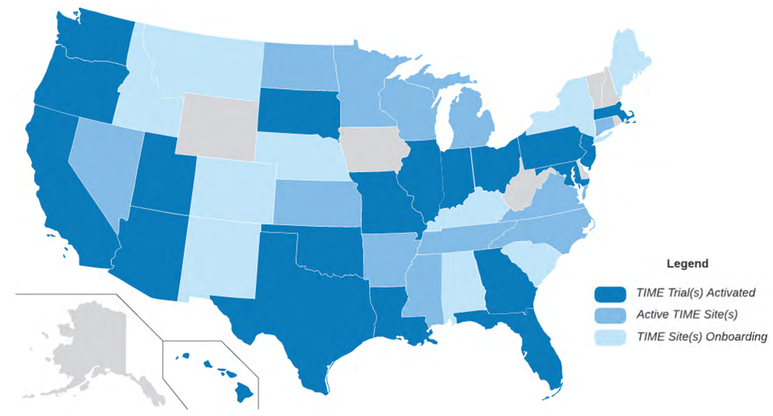

Figure 2. TIME Network Heat Map illustrating states where:
1. TIME Trials Activated have clinical trials open through the TIME Network
2. Active TIME Sites are fully onboarded and matching patients
3. TIME Sites Onboarding are completing feasibility requirements

Figure 3. JIT TIME Trial Site Activation Case Study

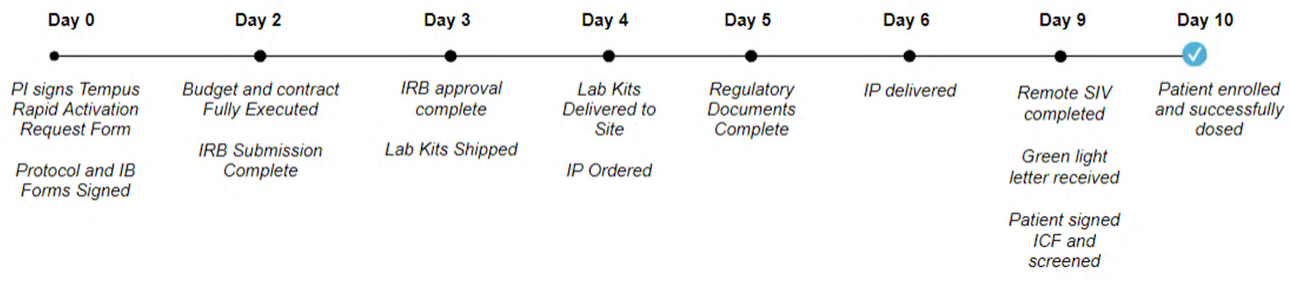

Figure 3. Rapid Activation of a TIME site trial in October 2020. IRB submission to approval was 1.2 days. Activation initiated to fully executed contract was 2 days. The patient consented and screened the same day as site activation and first dose was administered the following day.

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