CASE STUDY

Sequencing Case Studies

Through our highly automated CAP-accredited and CLIA-certified lab, Tempus provides access to a portfolio of comprehensive genomic profiling services for a variety of biopharma sequencing needs, including:

01 Prospective Sequencing for Clinical Trials

02 Retrospective Sequencing and Analyses

03 Companion Diagnostic Development

04 Sponsored Testing

The following pages contain a case study from each of these four offerings where Tempus serves as an NGS or diagnostic partner to life sciences companies.

01 Prospective Sequencing for Clinical Trials

Excellent communication and project management, innovative culture.

SITUATION

A biopharma partner came to Tempus seeking help to determine eligibility for their phase 2 clinical trial. The eligibility criteria for the trial included variants in specific regions of interest across four different genes determined through both DNA and RNA sequencing inputs.

The partner was looking for a vendor that could customize sequencing reports based on the biomarker eligibility criteria and deliver the investigational results to trial investigators. An additional area of interest for the partner was identifying altered splicing events in the four genes of interest for potential trial enrollment.

SOLUTION

Tempus has supported the partner's clinical trial enrollment in the US and across Europe, and delivered on the following services which were pivotal to Tempus being selected as their diagnostic partner for the study:

- Tempus' ability to build a new RNA pipeline, altered splicing, to increase the funnel of patients that are eligible for the trial
- Use of both DNA and RNA inputs to determine potential eligibility for the trial
- Access to Tempus' robust dataset to explore other therapeutic areas and trial expansion into other areas
- Support from TIME/Connect to help identify potential study subjects and allow them to obtain information about this trial
- Tempus' custom reporting outputs provide principal investigators with information about a patient's potential biomarker eligibility for a trial

RESULTS

Tempus' altered splicing pipeline resulted in the ability to identify additional patients who may be eligible for enrollment into this trial. Tempus developed this specialized pipeline to meet the partner's needs within just six months.

To date, turnaround time for Tempus' DNA and RNA sequencing is less than 14 days, supporting efficient trial eligibility information. Tempus is supporting 30+ clinical trial sites for the partner across Europe, Israel and the US, and has CE marked the assay to be able to assist with trial eligibility matching for European sites.

02 Retrospective Sequencing and Analysis

SITUATION

A large pharma company was looking for a partner that could provide custom analytics supported by multimodal data in addition to a reliable sequencing partner for several clinical programs including a large registrational study for NSCLC.The goal of the program was to ingest and develop gene expression signatures that could be applied to Tempus Sequencing data.

SOLUTION

Tempus has supported retrospective sequencing of hundreds of batched samples for this partner using our xT panel and RNA whole transcriptome sequencing. We have also identified and implemented several gene expression signatures in close collaboration with this partner, leveraging our database, such as:

- IFN Activity scores, including IFNgamma signature from Ayers et al., 2017 and IFNg signature (Beaubier 2019)
- STK11 loss signature (Kaufman 2014)

- NRF2 activation signature (Singh 2021)
- Thorsson immune subtypes (Thorsson 2018)
- TMB calculated from all variants
- Neoepitope burden, normalized by sequencing length
- MSI % unstable loci
- HRD (Myriad and Tempus methods)

RESULTS

By utilizing our internal database we can easily ingest and develop gene expression signatures and apply it to Tempus sequencing data through add-on analysis.
We successfully delivered our standard sequencing deliverables and bespoke analysis packages for 100s of samples to date, which the partner is using to inform their biomarker strategy for future trials.

> Mature, comprehensive data pipeline, willingness and capability to add custom analyses. Very easy to work with.

03 Companion Diagnostic Development

SITUATION

A biopharma partner approached Tempus seeking a solution to identify mutations leading to the loss of one normal copy of their gene of interest in patients with solid tumors. The biopharma partner is developing innovative cell therapies for cancer patients with solid tumors, and was looking for a sequencing and diagnostic partner that offered both DNA and RNA sequencing in addition to advanced analytics capabilities. The biopharma partner was also keen to develop a partnership with Tempus, to support the development of companion diagnostics for this asset and future products in their portfolio.

SOLUTION

- Tempus worked closely with the biopharma partner to understand the specific areas of interest in patients with solid tumors and how we could leverage our xT assay for this biomarker strategy.
- The biopharma partner was impressed with Tempus' comprehensive immunotherapy platform including, but not limited to: immune infiltration, neoantigen prediction, tumor mutational burden (TMB), microsatellite instability (MSI), HLA typing, HLA LOH, TCR & BCR repertoire, and oncoviral detection.
- Using Tempus' immunotherapy platform and extensive multimodal data, we were able to design a suitable biomarker for the cell therapy across solid tumors.
- Tempus' experienced regulatory affairs team supported the biopharma partner in trial design and submitted a Q-submission to align with the FDA on analytical and clinical validation approaches.

RESULTS

Tempus' computational immunology team designed a novel algorithm for solid tumor patients. Our R&D and regulatory teams have designed a validation plan for the CDx development. We are working with the partner and FDA to prepare for analytical validation, eventual clinical trial enrollment sequencing, and a supplemental PMA submission.

The biopharma partner selected Tempus as a companion diagnostic partner for this study due to the breadth and depth of our NGS testing platforms (broad panel, IO metrics and many different alteration types), in addition to the additional services Tempus offers including our comprehensive immunotherapy platform, multimodal dataset, plus our regulatory and post commercialization support services.

> The technology, innovation, and staff are second to none. It is a pleasure to work with such a talented and capable team.

04
Sponsored Testing

> The professional project management and response time to queries is fantastic and helps us do our job better. We love the project management and operations team! The additional analytical support is also phenomenal and critical to why we want to stay working with Tempus.

SITUATION

A large pharma company approached Tempus seeking a solution to identify more patients with a rare oncology biomarker. The company had a desire to improve access to genomic testing through this partnership, and wanted an accurate test which offered the detection of both DNA and RNA alterations. Additionally, the company needed a partner with significant clinical presence across the US, where many doctors are already familiar with the tests provided through the program.

SOLUTION

- Cooperative Engagement — The company identified physicians who would be eligible to participate in the program. Tempus provided education and support to help physicians understand how to order company-sponsored testing.
- Marketing and Public Statements — Tempus prepared a landing page on its website for HCP education about the program, and worked with the company to develop co-branded HCP educational materials. Tempus social media accounts were used for further awareness of the company-sponsored program.
- Operational Details — The company provided ordering physicians with a voucher that could be used to redeem tests. Tempus acted as the sequencing provider, and physicians were provided with a standard Tempus Clinical Report.

RESULTS

Tempus collaborated with the pharma company across sales and marketing initiatives to spread awareness of genomic testing and precision medicine with specialty physicians and patients more broadly through many different channels. Tempus provided gold-standard sequencing services using our xT panel and delivered clinical reports to physicians with an average ~10 day TAT.