Optimizing choice, flexibility and outcomes with Patient-First Data Collection for Oncology

Medable Oncology Overview

Traditionally, Oncology trials placed a heavy burden on patients due to travel burden, poor patient experience and multi-year clinical trial commitments. Sites also struggle with cancer trials due to enrollment delays, complex data workflows, and multiple amendments requiring re-consents. Today, we have a more effective, patient-first solution.

Optimize patient choice, improve retention and safety with Patient-First Oncology solutions that meet patients where they are.

Executive Summary

A top 5 global pharma company with a strong Oncology focus was seeking a partner to help improve clinician oversight of patients between site visits. They wanted clinicians to be able to monitor patients remotely for key signs and symptoms that could be an early indication of an adverse event that may require intervention, and be able to prompt the necessary course of action.

In a traditional brick and mortar trial, the study team would have to rely on weekly patient monitoring during the dose escalation period - and on a Monthly or Quarterly basis during the follow up period.

Medable decentralized solutions can dramatically enhance clinician oversight and patient safety by performing daily lung function measures and ePROs remotely through the entire study. Site clinicians are then able to detect early signs of potentially life threatening adverse events earlier than ever before.

Medable Solutions Deployed: eCOA and Sensor integration

1

7X

frequency in measurement during dose escalation with daily monitoring and expansion vs. traditional approach (every 7 days)

2

Up to

90X

frequency in measurement during follow up with daily monitoring vs. traditional approach (every 30–90 days)

3

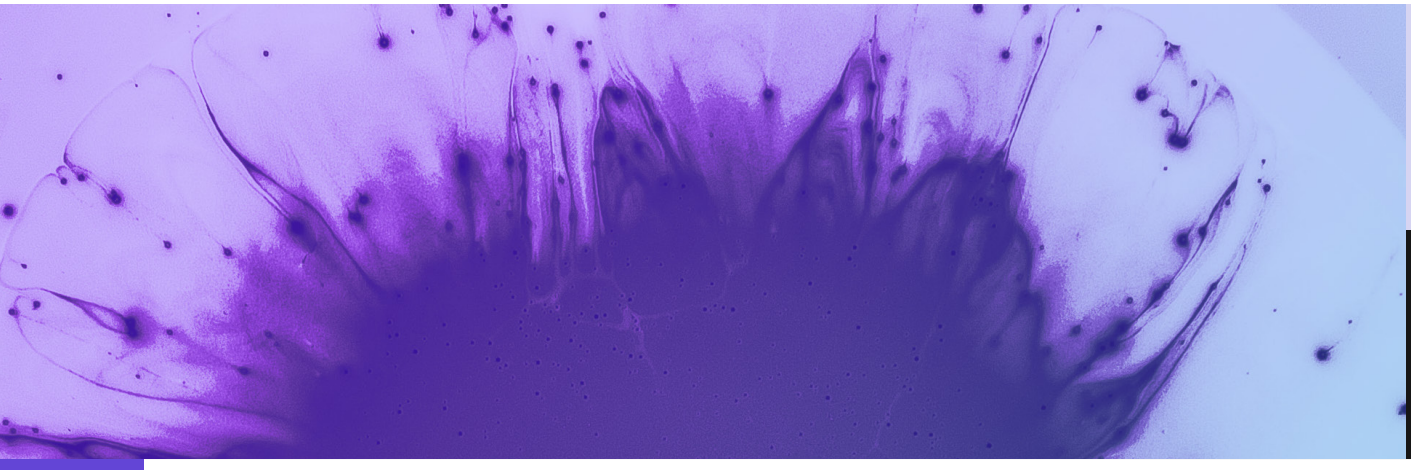
with the aim of

10-20%

of patients receiving more timely intervention that ultimately improves their outcomes

Sponsor Benefits

- Ability to better manage toxicity and tolerability in real time through Pulse Oximeter.
- Enhanced patient safety as a result of increased frequency of lung readings and the study sites' ability to review patient generated data in real time (per data transfer agreements)
- Optimize patient retention by reducing travel burden for patients
- Be seen as Sponsor of Choice in terms of additional patient-first safety monitoring



The Problem

A top 5 pharma company wanted to increase the safety of patients. It is known that anticancer treatments may cause pulmonary toxicity, ranging from asymptomatic radiological changes to respiratory failure, and is considered a common side effect.

Typically an assessment of lung function is performed as part of the regular visit schedule, and could range from weekly, during dose escalation and monitoring, to every 30-90 days, during the Follow Up Period.

The Solution

Medable's decentralized clinical trial (DCT) platform, with modules for eCOA and sensor integration was leveraged to track daily lung function and related symptoms. Data from the frequently collected measures, along with a daily symptom diary, were captured and reviewed by remote clinical staff. This review could trigger additional questionnaires and further in-person testing.

Medable's customer success team worked diligently to ensure that the solution implemented was easy to use, and provided reliable data to safety monitors and study teams.

The solution had to be:

- **Easy to Complete:** patients were asked to complete daily diaries with a connected sensor so it was critical that the data capture workflows be intuitive and easy
- **Actionable Data:** The data captured had to be available in real time for sites to review, which allowed them to flag patients for potential follow up earlier than ever before
- **Trigger Based ePROs:** When a case was suspected, monitors needed the ability to trigger additional ePROs to capture relevant HRQoLs

The Sensor Integration

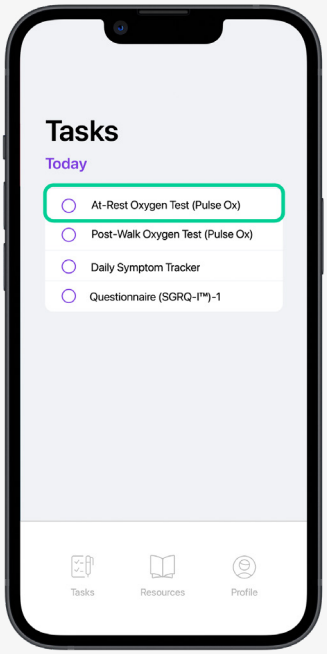
Medable's connected device team worked closely with the sponsor to vet and select the appropriate SpO2 device for this study. The team performed an in-depth analysis that covered:

- Data flow
- Ease of use and patient feedback
- Logistics and shipping
- Regulatory status (e.g. 510k)
- Integration type (Direct vs. API)
- Operating conditions (battery life, operating temperature, etc.)
- Range of assessments in a single device

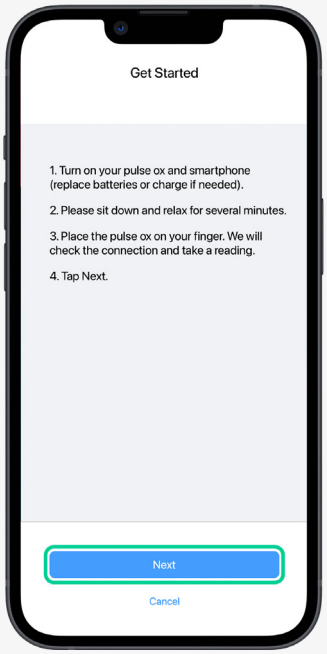
With the sensor selected, device kits were shipped to study sites across the globe to 24 different countries, including sites in Europe, Asia, and North America.

The Data Capture Workflow

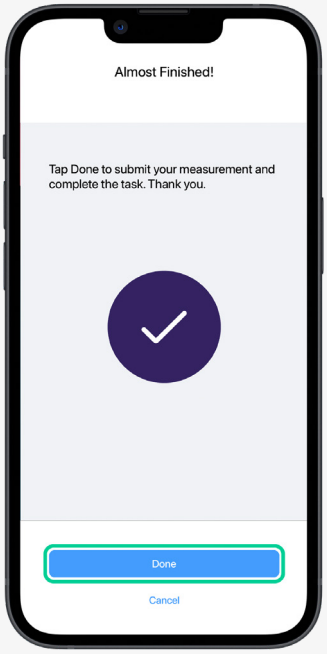
With the device vetted and selected, the team then worked on creating an easy experience for patients to enter data. Patients were able to use their own device (BYOD) or if they preferred, a provisioned device was provided. Using a mobile app, patients were shown daily tasks that guided them through performing the lung function measure and daily diary.



Patients select the task needed to be performed.

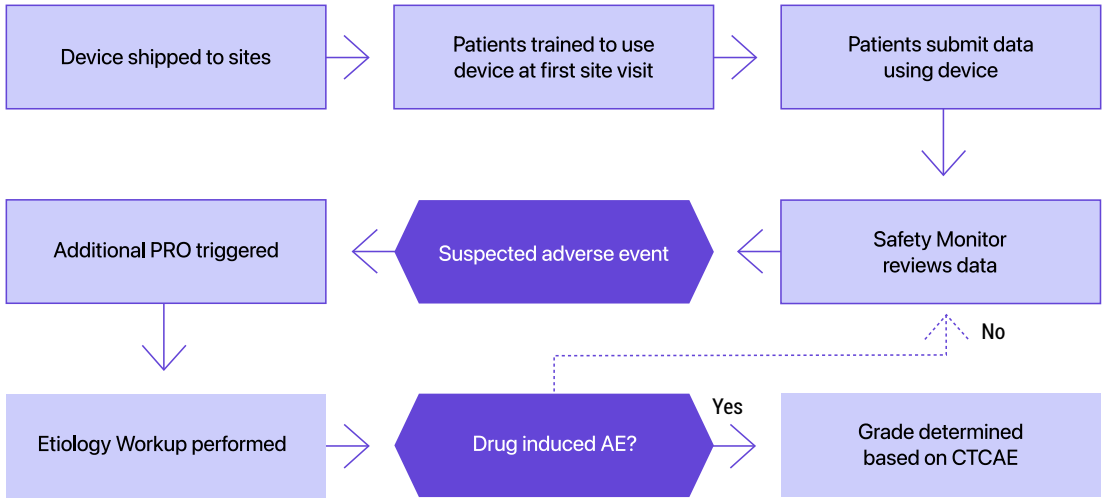


Easy to follow instructions were provided to patients, walking them through the measurement.



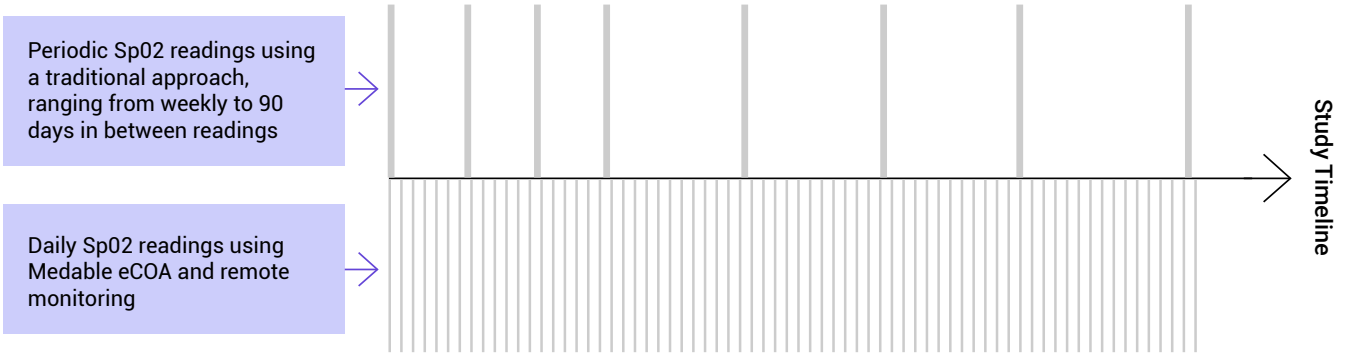
Data sent to the app via bluetooth uploaded platform in real time.

The Approach



The Results

Studies in the portfolio began going live in Q4 2020 and are currently enrolling patients. Feedback from sites and the sponsor has been extremely positive, with patients successfully performing remote sensor readings and patient diaries as needed. Most importantly, patient oversight has been greatly enhanced as a result of increased frequency of lung function readings and the sponsor's ability to review patient generated data in real time.



(Adapted from Digital Medicine Society, 8)

Questions? Reach out to Medable Oncology Team

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