ctDNA Portfolio Development and Milestones

ctMoniTR Step 1

STEP

Research partnership with 5 NSCLC trials (200 pts) ctMoniTR Step 2

Expanded research partnerhship with >20 trials (>3000 pts) Evidentiary Roadmap

ROAD

Roadmap of evidence to support regulatory use of ctDNA Baseline

Research partnership determining baseline ctDNA levels

2018-2021

2022

2023 and beyond

5

FALL 2018

ctDNA for monitoring treatment response discussed during the Friends' Annual Meeting.

SPRING 2019

ctMoniTR Step 1 initiated to align on datasets and select an independent analysis center.

SUMMER 2020

Step I findings presented presented showing decreases in ctDNA are strongly associated with better clinical outcomes in 5 clinical trials of 200 patients with NSCLC treated with immunotherapy.

SPRING 2021

ctMoniTR Step 2 launched with a goal of developing and analyzing a larger dataset.

Step 2 datasets finalized and include over 3000 patients from more than 20 clinical trials.

SPRING 2022

SPRING 2022

Friends hosted roundtables to discuss evidentiary needs to support the regulatory use of ctDNA as an early endpoint.

SUMMER 2022

Public meeting held to present findings from the evidentiary roadmap.

SUMMER 2022

Findings from Step 1 published in JCO Precision Oncology.

FALL 2022

Baseline ctDNA Project initiated to describe baseline ctDNA levels across cancer types, stages, and assays.

WINTER 2023

Planned analysis and submission of initial Step 2 findings for presentation in O2

2023 AND BEYOND

Complete analyses from Step 2. Present finalized results at meetings and publish manuscripts.

2023 AND BEYOND

Identify opportunities to incorporate analyses developed through ctMoinTR in additional prospective studies.

2023 AND BEYOND

Perform meta-analysis of baseline ctDNA levels and aid the use of ctDNA as an endpoint in different cancer types.

