



Friends of Cancer Research Launches Next Step in Real-World Evidence Initiative

Pilot Project Will Provide Novel Analysis in Partnership With 10 Leading Healthcare Research Organizations

Friends of Cancer Research (*Friends*) is launching the next phase of our Real-World Evidence (RWE) pilot project after a [broad stakeholder meeting](#) in February 2019. At the meeting, FDA and various data partners expressed interest in continuing to address several challenges to advance our understanding and inform future uses of RWE. This next phase includes 10 healthcare research organizations that will be presenting their findings, establishing recommendations for real-world endpoint analysis, and evaluating whether real-world endpoints are indicators of clinical benefit at this year's [8th Annual Blueprint for Breakthrough Forum](#), which will be co-hosted with [Alexandria Real Estate Equities](#) on September 18th.

Friends is continuing its work to solve issues related to the use and understanding of RWE through this project by using our existing framework to assess several frontline treatment regimens in real-world patients with advanced non-small cell lung cancer (aNSCLC). This pilot project includes three proposed analytic objectives:

- **Description of demographic and clinical characteristics of patients with aNSCLC.** This will provide a baseline understanding of the similarity/differences among the datasets to better understand what confounding factors may need to be considered when interpreting the data.
- **Evaluate select real-world endpoints among PD-(L)1-containing frontline therapy regimens.** This will assess the ability of real-world endpoints to measure differences in treatment effect size in frontline treatment regimens in aNSCLC while also evaluating the ability of these real-world endpoints to detect differences in subgroups and treatment.
- **Develop a framework proposal to assess performance of real-world endpoints in a given dataset.** This will evaluate the robustness and validity of real-world data (RWD) to support the integration and utilization of RWE in regulatory decisions.

The initial *Friends'* RWE pilot project demonstrated that different datasets could be used to extract several real-world endpoints in a relatively consistent manner. In order to further characterize the role real-world endpoints may play in measuring treatment effect size, pilot project 2.0 will examine the ability of different real-world endpoints to detect treatment effectiveness in real-world patient populations. Additionally, data from this pilot project will help inform a framework containing key data elements, endpoint definitions, and algorithms that could be applied to other datasets representing different therapeutic areas and disease types.

10 Healthcare research organizations and additional stakeholders participating in this pilot project

include: Aetion, ASCO CancerLinQ, Cancer Research Network, COTA, FDA, Flatiron Health, IQVIA™, Mayo Clinic, McKesson, NCI SEER-Medicare Linked Database, OptumLabs®, Syapse, Tempus

For more information on the project, including information on last year's phase of the pilot project, [please click here](#).