INTRODUCTION

Nonalcoholic fatty liver disease (NAFLD) is highly prevalent in both children and adults. NAFLD can lead to cirrhosis, hepatocellular carcinoma and death from liver disease. NAFLD is also associated with increased risk of type II diabetes and cardiovascular events. Current treatment goals, limited to exercise and weight loss, are difficult for many patients to achieve and maintain. Thus, pharmacological therapies are greatly needed; many are in various stages of development. Large, observational cohorts are needed to better understand the spectrum of NAFLD by obtaining real-world data that avoids ascertainment bias from studies in tertiary care centers alone and allows for further validation of histology and non-invasive biomarkers. The overall aim of TARGET-NASH is to determine the natural history of NAFLD and to assess as are adverse outcomes, including cardiovascular and neoplastic pathology, imaging data and patient-reported outcomes, is abstracted into a centralized medical record from consented patients including narratives, laboratory results, combined pathology, imaging data and patient-reported outcomes, is abstracted into a centralized pathology, imaging data and patient-reported outcomes, is abstracted into a centralized

METHODS

TARGET-NASH is an observational study, initiated in 2016, of pediatric and adult patients with NAFLD managed at academic and community Hepatology, GI and Endocrinology practices. The medical record from consented patients including narratives, laboratory results, pathology, imaging data and patient-reported outcomes, is abstracted into a centralized data core. Detailed demographics, patient comorbidities, medications and disease progression are assessed as are adverse outcomes, including cardiovascular and neoplastic complications. Data from the first 1300 consecutively enrolled patients are presented. Descriptive statistics with ANOVA and Cochran-Armitage tests for trend are reported.

TARGET-NASH SITES

DISEASE CATEGORY DEFINITIONS

NAFL
- Any participant with hepatic steatosis not meeting criteria for clinical NASH or cirrhosis

NASH
- Confirmed by biopsy:
  - Steatohepatitis by Brunt criteria OR NAS total score ≥ 4
  - Clinical diagnosis:
    - ALT > 50 U/L for adult female (≥22 y) ≥ 30 U/L for adult male (≥18 y) and;
    - Hepatic steatosis on biopsy or CT/US/MRI and;
    - ≥ 1 of the following BMI ≥ 30, type II diabetes, dyslipidemia

NAFLD Cirrhosis
- 1) Liver biopsy with fibrosis stage = 4 OR
- 2) Liver biopsy with fibrosis stage = 3 and ≥ 1 clinical signs of cirrhosis OR
- 3) ≥ 2 more clinical signs of cirrhosis OR
- 4) FibroScan® stiffness result ≥ 11 kPa

CONCLUSIONS

- Participants enrolled in TARGET-NASH include populations, such as patients with cirrhosis and cardiovascular disease, not widely represented in clinical trials.
- Real-world clinical registries are important for obtaining unbiased natural history data and determining clinical effectiveness of new interventions.
- TARGET-NASH will be an important source of real world patient oriented outcome data.

STATEMENT & DISCLOSURES

TARGET-NASH is a collaboration among academic & community investigators, the pharmaceutical industry, and NAFLD patient community advocates. TARGET-NASH is sponsored by TARGET PharmaSolutions, Inc. TARGET thanks the study staff, nurses, health care providers and patients at each study center for their contributions to this work. Listings of Principal Investigators and Industry Partners are available upon request by emailing info@targetpharmasolutions.com.