Key Findings

- Clinicians overwhelmingly cited multiple needs for new or improved medical devices for diagnosing and treating rare diseases
  - 461 unique rare diseases were cited with 917 specifying unmet device needs
  - 91% believed a new or improved device is needed
  - 64% were dissatisfied with existing diagnostic and/or therapeutic devices

- There is a critical need for entirely new devices rather than modifying or repurposing devices, which are often inadequate
  - 77% cited a need for an entirely new diagnostic and/or therapeutic device
  - 23% cited a need for only modified or repurposed diagnostic and/or therapeutic devices

- Existing devices have several limitations in diagnosing or treating rare diseases
  - 79% reported diagnostic devices for genetic disorders as an unmet need
  - 37% currently repurpose an FDA-approved therapeutic device

- Several impediments to developing new devices for rare diseases were mentioned
  - 74% saw the lack of profitability to industry as a large impediment
  - 67% saw the cost of development as a large impediment

- The Humanitarian Device Exemption (HDE) provides a helpful pathway for bringing devices to market, but there are obstacles to its use.
  
  Top challenges cited by the 51% of respondents reporting familiarity with HUD/HDEs include the following:
  - 52% said reimbursement
  - 50% reported gaining access to HDE devices
  - 46% indicated institutional review board constraints

- While there are unique pediatric challenges, respondents with pediatric experience reported high levels of dissatisfaction similar to those without pediatric experience
  - 33% of clinicians had a pediatric focus
  - 66% believed there is a pediatric need for implants that grow along with the child
  - 44% confirmed intrathecal ports for drug delivery confirmed as a pediatric need