OBJECTIVE
Assessing the extent that the Best Pharmaceuticals for Children Act (BPCA) advances pediatric clinical trials (CTs) and the availability of pediatric-specific drug information.

BACKGROUND

**Key Pediatric Legislations and Policies**

- **2002: Best Pharmaceuticals for Children Act (BPCA)**
  - Allowed U.S. Food and Drug Administration (FDA) to request manufacturers for pediatric CTs for previously approved drugs.
  - Manufacturer’s participation is voluntary, not mandatory.
  - Incentivized by additional marketing exclusivity.

- **2003: Pediatric Research Equity Act (PREA)**
  - Provides FDA with authority to require pediatric studies of drugs and biologics currently reviewed by FDA.

- **2012: Food and Drug Administration Safety and Innovation Act (FDASIA)**
  - Made BPCA and PREA permanent legislations.

**Clinical Trials and Pediatric-Specific Drug Trials Snapshots: Age data, Pediatric and Adult, Pediatric Only, and Specific Pediatric Populations Only**

**Drug Trials Snapshots: Age data, Pediatric and Adult, Pediatric Only, and Specific Pediatric Populations Only**

**CONTACT**

**OBJECTIVES**

- To assess the extent that the BPCA advances pediatric CTs and the availability of pediatric-specific drug information.

**METHODS**

- **BPCA Drugs**
  - Searched Clinicaltrials.gov for CTs relating to drugs approved under BPCA in 2016 to 2018 period.
  - Categorized by study eligibility: Pediatric and Adult, Pediatric Only, and Specific Pediatric Populations Only.
  - Calculated number of pediatric participants from age data and assessed for trends.

- **Non-BPCA Drugs**
  - Searched FDA.gov for New Drug Applications (NDA) related to Pediatric indications and Pediatric studies in 2016 to 2018 period.
  - Collected from approved drug labels and Drug Trials Snapshots: Age data, Pediatric indications, and Pediatric studies.
  - Examined data for similarities and trends.

**CONCLUSIONS**

- **Low levels of pediatric subjects for studies completed under the BPCA, especially those open to adults and pediatrics.**

- **An increasing trend of conducting CTs, where adults and pediatrics are eligible, compared to pediatric only and pediatric subpopulations for both BPCA and non-BPCA drugs.**

- **A correlation between drugs initially seeking a pediatric indication via the NDA pathway (aka non-BPCA drugs) with higher pediatric subject enrollment and retention vs. BPCA drug studies.**

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