

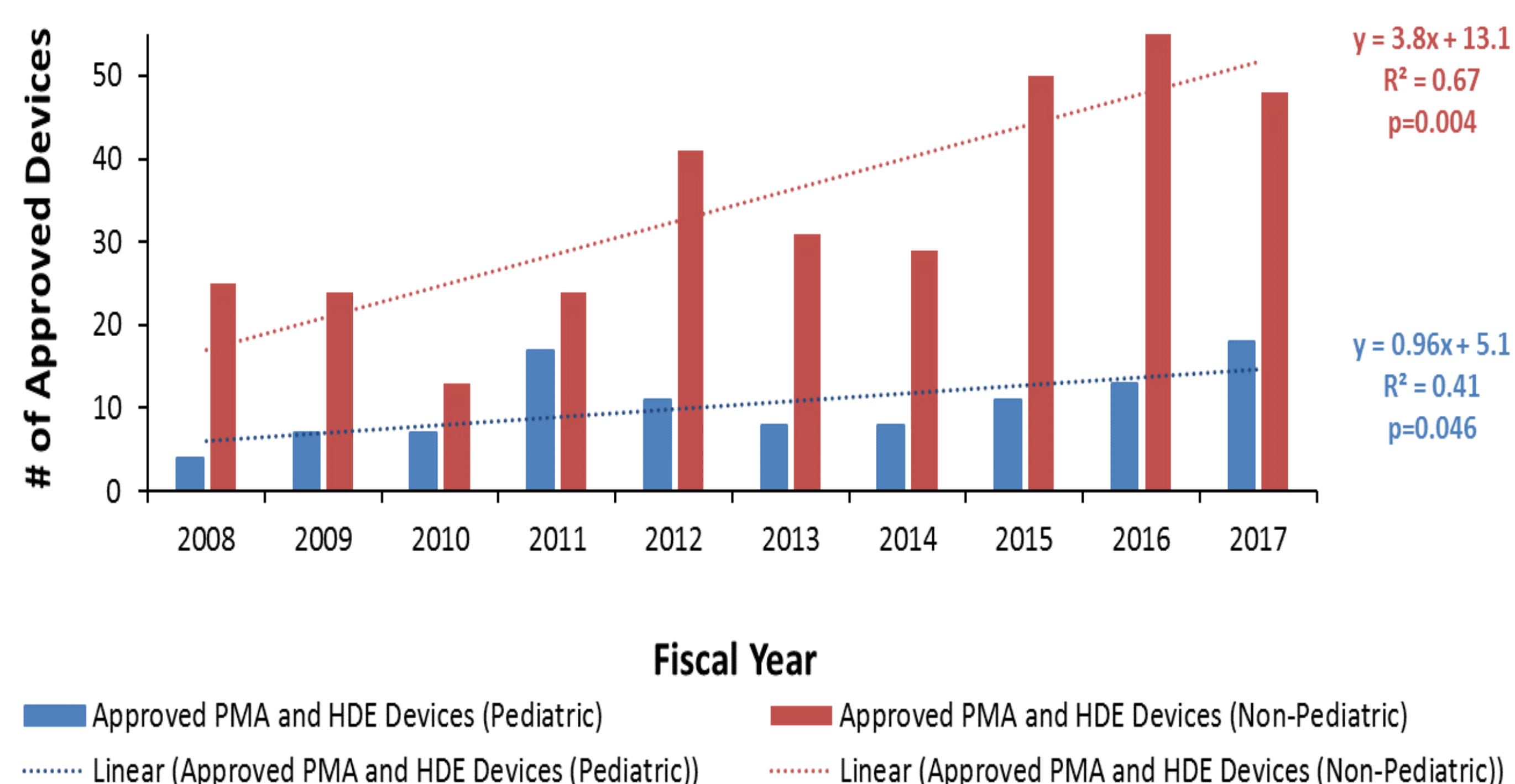


FDA's Pediatric Device Consortia (PDC) Grants Program: Narrowing the Gap in Pediatric Medical Device Development

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Introduction: Medical device development for children continues to lag behind that for adults (Figure 1). A need exists for pediatric devices, including those designed for children as well as existing adult devices adapted for pediatrics.

Figure 1. Rate of Adult Devices compared to Pediatric Devices

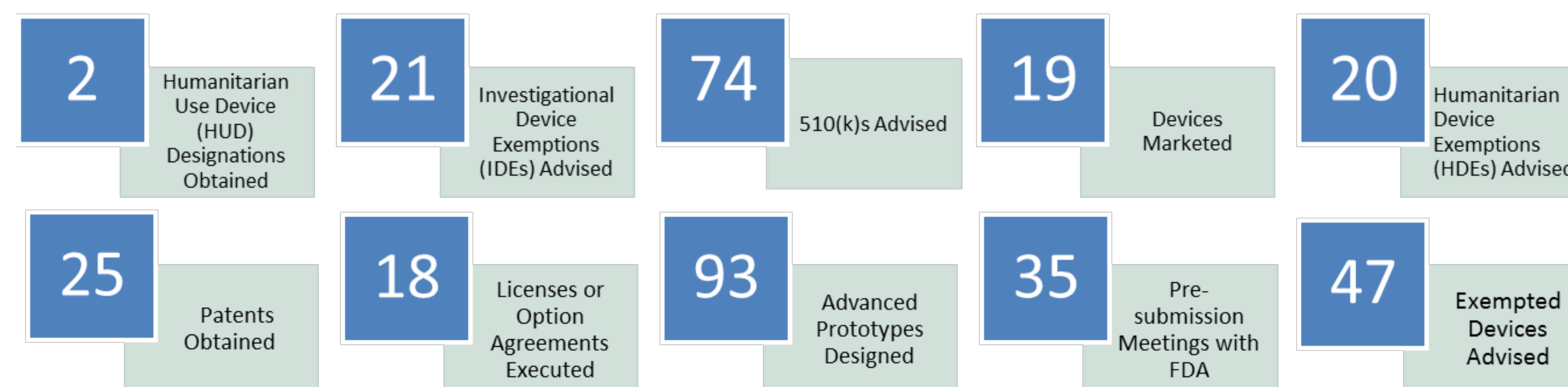


Bar graph showing the slower pace of pediatric medical devices to market. From M. McCorry, 2018, *FDA Numbers and Facts Pediatric Medical Devices*.

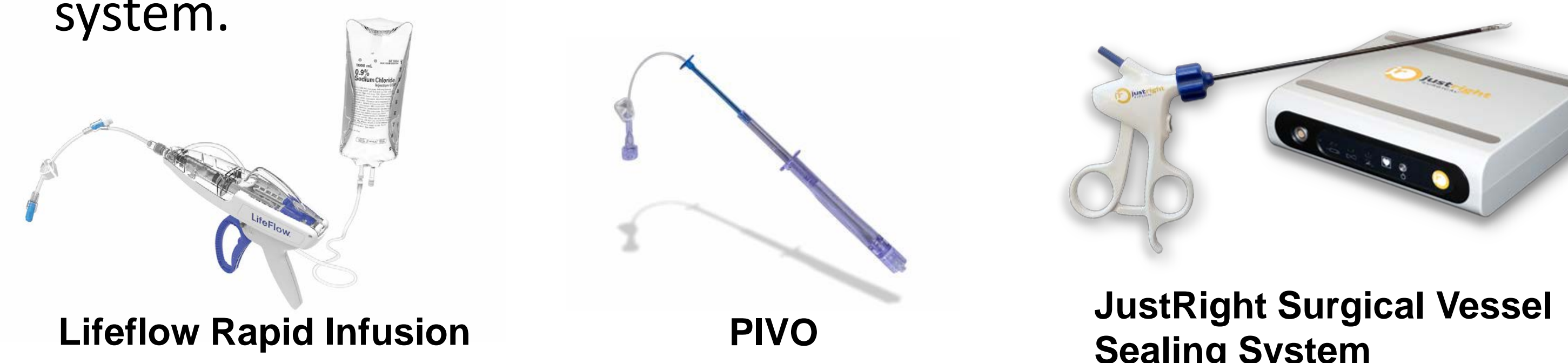
Methods and Results: The development of pediatric devices is underserved compared to adult devices due to factors such as relatively low return on investment, unique design considerations, small market and small sample size, reimbursement considerations, etc. To address these unique challenges, the PDC Grants Program was created by Congress under the Pediatric Medical Device Safety and Improvement Act of 2007 and is administered by FDA's Office of Orphan Products Development (OOPD). Staff within OOPD and the Center for Devices and Radiological Health work closely with the PDC grantees and pediatric device innovators to increase the development, awareness, and production of pediatric devices.

OOPD has awarded grants in 2009, 2011, and 2013 totaling \$31.4M since the program's inception. The FDA Reauthorization Act of 2017 reauthorized the PDC Grants Program for an additional 5 years and codified that consortia shall provide regulatory consultation to device innovators in support of applications to the FDA for pediatric devices.

Figure 2. Cumulative PDC Metrics



As a direct result of FDA funding, the PDC has assisted over 800 device projects and brought a total of 19 devices to market as well as accomplished other device development successes (Figure 2). Examples of devices on the market include the PIVO, a needle-free blood collection device that attaches to peripheral IV systems; the JustRight Surgical Vessel Sealing System designed for use in open and laparoscopic general surgical procedures to seal blood vessels and vascular bundles; and the Lifeflow Rapid Infusion to deliver fluids to a patient's vascular system.



The FDA awarded five new consortia across the United States (Figure 3) on September 1, 2018 totaling up to \$6M/year over the next five years. Of the estimated \$6M/year, approximately \$1M/year will be used for the Real World Evidence (RWE) Pediatric Demonstration Projects where three consortia will conduct projects that develop, verify and operationalize methods of evidence generation, data use and scalability across device types, manufacturers, and the health care system.

Figure 3. 2018 Pediatric Device Consortia

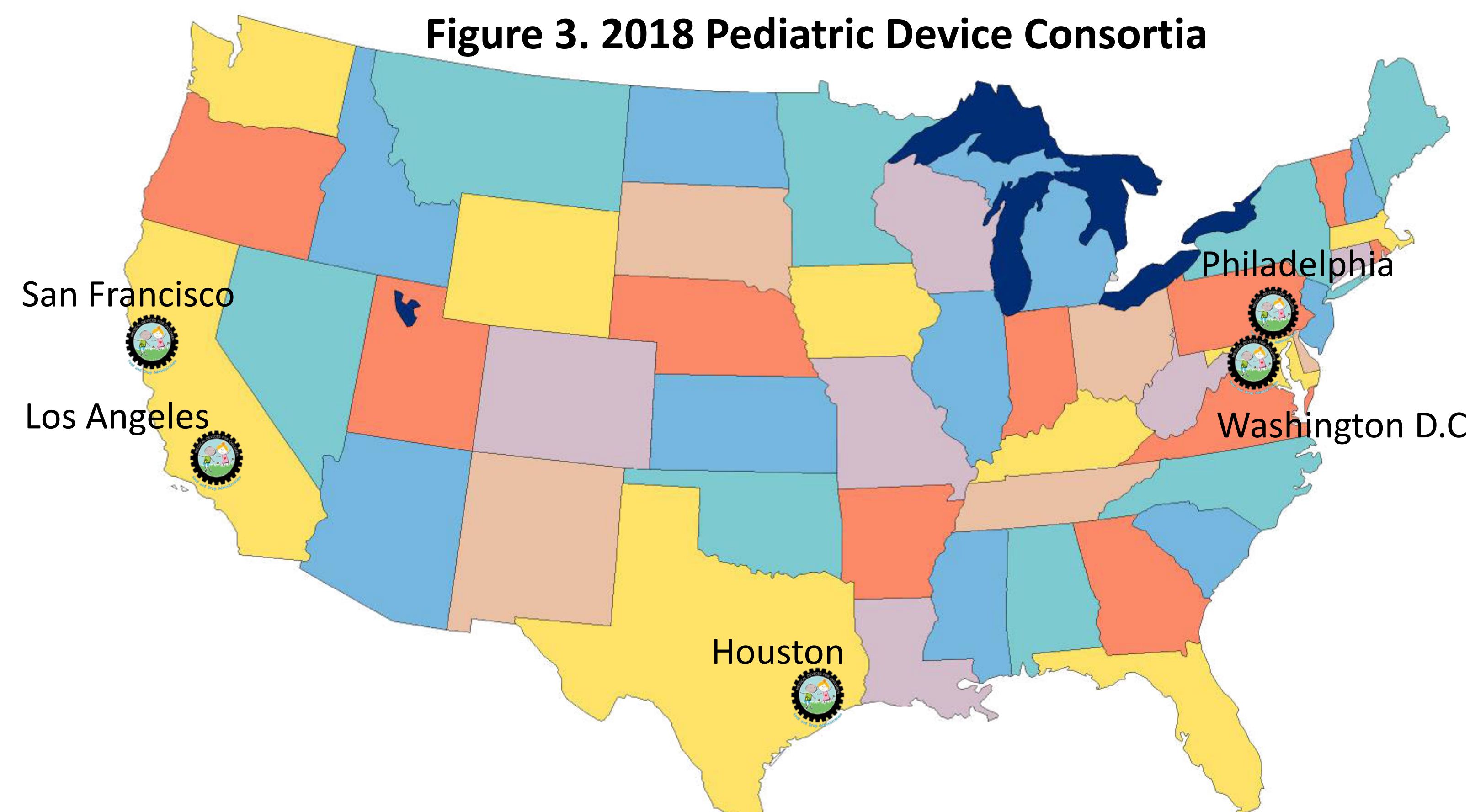
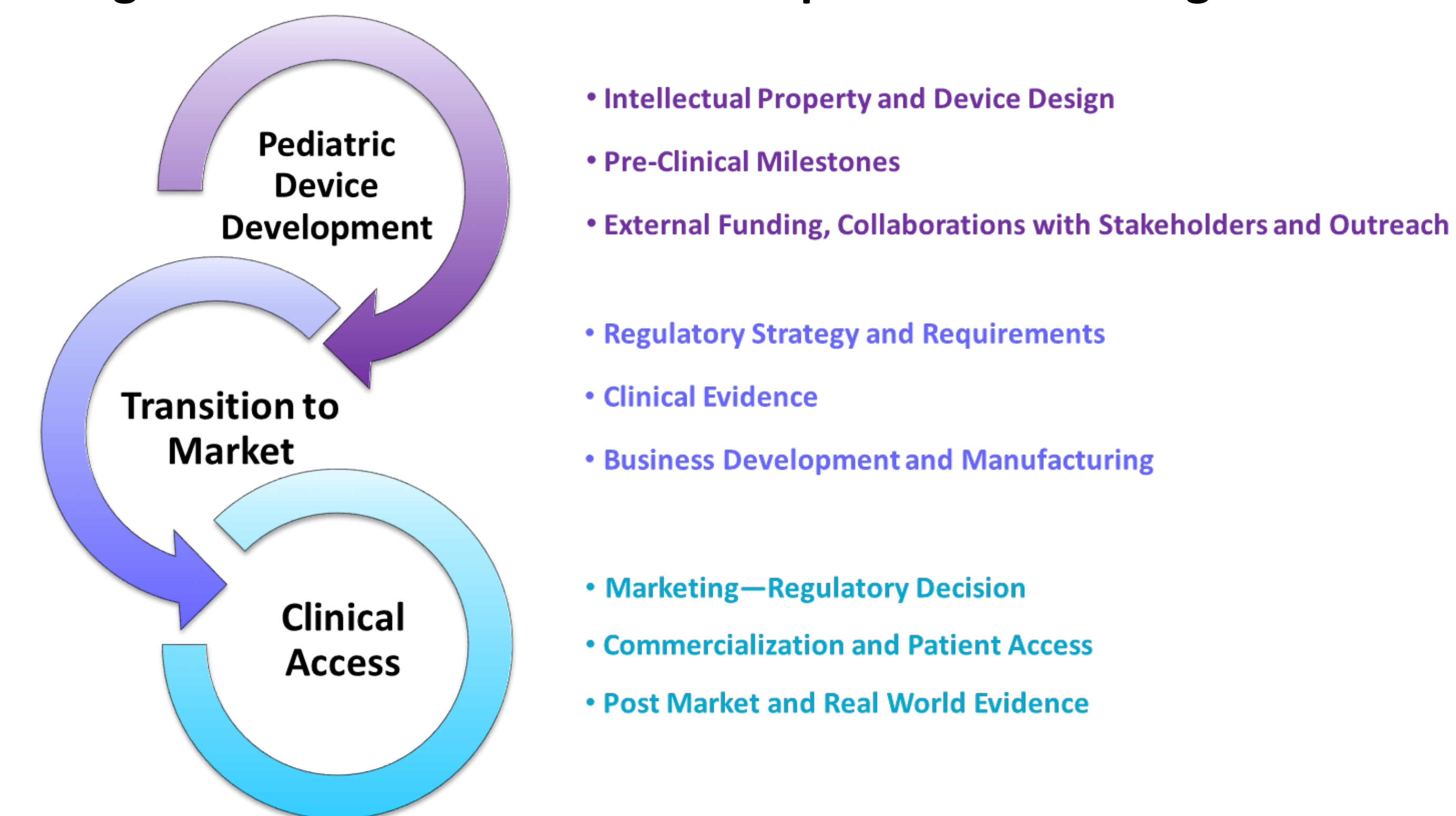


Figure 4. Consortium Success: Impact Metrics Categories



Conclusions: The unique challenges of developing and marketing medical devices for pediatric patients require support from consortia in leadership, expertise, and resources to pediatric device innovators. Since the program was established in 2009, the PDC have developed a national platform to advance pediatric device development that will benefit children and their families. OOPD will continue to oversee the program and with refined metrics (Figure 4) collect quantitative and qualitative achievements as well as impact narratives on device projects to communicate the advances in pediatric device development to community stakeholders. The PDC will also collect consortium level metrics as well as device project attributes (Figure 5) to further measure impact. FDA is committed to advancing policies to encourage the development of safe and effective medical devices designed specifically for pediatric patients and will continue to work to encourage device innovation for medical conditions that impact young populations.

Figure 5. Device Project Attributes

