

Real-World Data (RWD) Collection and Innovative Decentralized Approaches – Putting the Patient First and Enhancing Patient Diversity

SA77

Henderson J¹; Proulx K¹; Fillingham S²; Gwadry-Sridhar F¹
¹Pulse Inframe, USA, Canada ; ²PIP-UK, UK
Email: hello@pulseinframe.com

PROBLEM

Patients, manufacturers, regulators, and payors have recognized the need for greater access and diversity in real-world data (RWD) registries. To facilitate participation from a global community, there are considerations and challenges related to patient recruit and engagement that should be considered.

DESCRIPTION

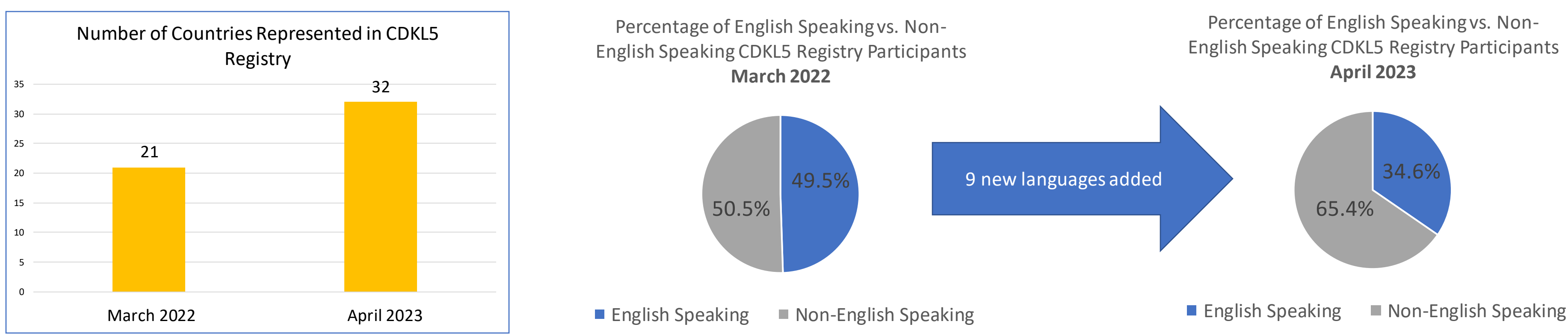
Participation in RWD registries is often constrained to institutions where participants are receiving care and which participate as sites. This limits enrollment to a handful of geographies, and often to academic institutions within these geographies. In addition to the physical distance, multiple factors affect participation, including the need to take time off work, to care for dependents and to understand the language of the registry. The research community is increasingly committed to developing solutions that can improve access and inclusion of patients in research. This is particularly important for rare diseases. We report two cases where web-based and multilingual approaches have accelerated participant enrollment and increased geographical and cultural diversity.

The Poland Syndrome Community Register (PSCR) and the CDKL5 (cyclin-dependent kinase-like 5) Registry are hosted on a flexible, cloud-based centralized platform that upholds regulatory, security, and privacy requirements to support worldwide collaboration. With PSCR, the decision was made to launch a registry that could support participation globally, while remaining compliant with data regulations. The web-based registry was initiated in January 2022, and currently includes 242 participants across 27 countries. After its launch in July 2018, a decision was made with the CDKL5 Registry to expand the web-based registry to nine additional languages in March 2022 to attract participants in non-English speaking countries. The number of countries represented by enrolled participants has grown 50% since the new languages were added, from 22 in March 2022 to 33 in April 2023. Participants in non-English speaking countries represent 84.1% of participants added to the registry in that same period (see Figure 2). The CDKL5 Registry now has over 160 participants.

Figure 1. Poland Syndrome Community Registry Growth



Figure 2. CDKL5 Registry Growth Following Multi-Lingual Approach



LESSONS LEARNED

Inclusion and diversity are enabled through decentralized and multi-lingual approaches. Participants can access educational material and visualize their data on dashboards, which supports retention. These approaches lead to more generalizable data for researchers. Insights from this work will inform future registry design.