REAL-WORLD EVIDENCE ALLIANCE

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July 25, 2024

Via Email

The Honorable Diana DeGette
2111 Rayburn House Office Building
Washington, DC 20515

The Honorable Larry Bucshon, M.D.
2313 Rayburn House Office Building
Washington, DC 20515

Re: Next-Generation Cures Request for Information

Dear Congresswoman DeGette and Congressman Bucshon:

Thank you for your leadership to advance next-generation treatments and cures. The RWE Alliance appreciates the opportunity to respond to your June 6, 2024, request for stakeholder input on ways Congress can continue to advance the 21st Century Cures initiative.

The RWE Alliance is a coalition of real-world data ("RWD") and analytics organizations with a common interest in harnessing the power of real-world evidence ("RWE") to inform regulatory decision making to improve the lives of patients. Our members have deep knowledge and experience working with healthcare data across disease areas and patient populations, and we aim to bring these collective insights to bear in support of RWE policies.[1] The RWE Alliance advocates for policies that will (1) advance FDA's RWE Framework, (2) encourage the use of RWE to better understand treatment effects in underrepresented populations, (3) enhance opportunities for RWE organizations to consult with FDA, (4) increase communication on the generation and use of RWE, and (5) recognize the unique aspects of and opportunities for RWD/E.[2]

As Congress recognized with the 21st Century Cures Act and previous iterations of Cures 2.0 legislation, RWE can play an important role in accelerating medical product development and delivering new treatments and cures more quickly and efficiently to the patients who need them. The 21st Century Cures Act enacted in December 2016 is

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[1] For information about our members, please see our website, https://rwealliance.org/who-we-are/.

[2] Additional information about what we believe is available on our website, https://rwealliance.org/what-we-believe/.

responsible for establishing the RWE Program at FDA and for setting in motion meaningful advancements in the use of RWE to benefit patients.[3]

We strongly encourage any future Cures legislation to expand upon these prior efforts to enhance the use of RWE. FDA has implemented the 21st Century Cures directives to establish an RWE program, to publish an RWE Framework, and to issue guidance for industry on the use of RWE in regulatory decision making, and Congress should consider whether new statutory directives would be helpful for advancing this important work.

Thank you for considering these comments and for spearheading the Cures initiative. We look forward to continuing to work with you to accelerate medical product innovation and improve patient care, including by advancing the use of RWE in regulatory decision making on medical product safety and effectiveness.

Best,

The RWE Alliance

[3] 21st Century Cures Act, Pub. L. No. 114–255 § 3022 (2016).