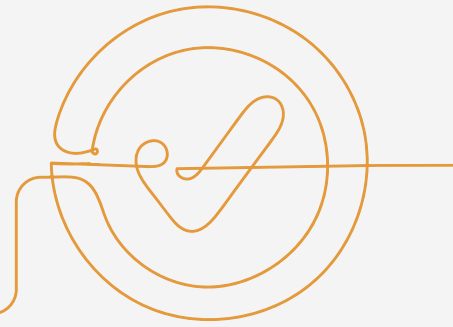


## Key Inclusivity and Accessibility Projects from the FDA's Oncology Center of Excellence



As part of the FDA's ongoing work to incorporate patients' perspectives into drug development (as well as biological products and devices), the agency launched its Oncology Center of Excellence (OCE) in 2017, shortly after Congress passed the 21st Century Cures Act.

The OCE unites scientific experts across the FDA to conduct expedited reviews of drugs, biologics, and devices to facilitate the development and clinical review of oncology products. The OCE also leads research and educational outreach projects and programs to advance the development and regulation of medical products for patients with cancer.

To date, the OCE has launched more than 300 programs and projects, ranging from dose optimization and research to diversity and inclusion. This piece will focus on OCE projects dedicated to increasing the inclusivity and accessibility of clinical research, along with a discussion of how these projects might assist your drug development efforts. Worldwide's Clinical Research Methodology team can also provide further guidance on how to use these programs to support your clinical development goals.

### **Project Equity: Diversity, Access, and Inclusion**

**Overview:** Multiple groups of people have long been underrepresented in clinical research. This includes racial, ethnic, sexual, and gender minorities, as well as individuals who live in rural areas. Clinical research participation has similarly lagged for people with economic, linguistic, or cultural barriers to accessing healthcare services.



**Key Intent:** Project Equity aims to improve access to oncology clinical trials for these underrepresented populations. The goal is to ensure that data submitted to the FDA for approval of oncology medical products adequately reflect the demographics of the populations who will ultimately use the product if approved.

Project Equity develops and promotes policies that encourage adequate enrollment of underrepresented populations and evaluates differences that may exist across study populations. Additionally, FDA staff members will engage with stakeholders on research, policies, and educational initiatives aimed at promoting access and advancing equity. Project Equity staff also conduct and publish comparative analyses of data generated through clinical trials to evaluate outcomes across demographic subgroups.

**How to Apply to Your Study:** A racial and ethnic diversity plan is a necessity in all late phase programs. This plan should start with inclusive study design and extend to all aspects of the study. For example, sponsors should:

- Review inclusion/exclusion criteria to ensure they are not overly limiting.
- Determine an acceptable site/country mix to meet inclusive demographic goals.
- Provide study sites with resources, training, and tools to ensure diverse recruitment.
- Create culturally appropriate study-related materials and translate them into languages commonly spoken at all study sites.

Ideally, sponsors will provide patient and family transportation, stipends, site accommodations, and other supportive services to encourage participation.

**Note:** Project Equity requirements are less strict for early phase studies, as these studies are smaller in size and often designed for hypothesis generation.

## **Project Silver: Senior Inclusion**

**Overview:** Adults over the age of 65 compose a growing segment of both the general and oncology populations. Age-based differences may affect drug response and toxicity, and older adults often have comorbidities and polypharmacy that could increase the incidence and severity of adverse events. Older adults also face increased study-related challenges compared to younger patients, including risks related to adherence, falls, or decreased cognition.



**Key Intent:** Project Silver works to increase the representation of older adults in cancer trials to improve their treatment, care, and outcomes. This includes the subset of adults 75 and older, who have often been excluded from clinical research.

Regulatory policy will encourage sponsors to conduct inclusive and representative trials. One goal is to develop and evaluate more nuanced geriatric assessment tools for physiologic age that better articulate a patient's true performance status. Project Silver additionally provides resources for advocacy and outreach to older adults to improve their healthcare access and understanding of treatment goals and outcomes.

**How to Apply to Your Study:** As with Project Equity, sponsors must attempt to match the clinical trial population to those most likely to receive the prescription after approval. Specific strategies include creating complementary or nested subgroup trials for drugs likely to be used by older adults. Sponsors should ensure that enrollment strategies are inclusive of older adults and should design robust trials to control for chronic conditions. Embracing advanced age as a complex factor in data analyses is also an effective strategy.

[Learn more about Project Silver](#) →

## **Project Orbis: International Access**

**Overview:** The FDA often receives new oncology product applications months to years before regulatory agencies in other countries. Pivotal clinical trials now often require a global footprint, so increased standardization and communication among global regulatory bodies increases the likelihood of concurrent drug approvals, thereby increasing patient access internationally.



**Key Intent:** Project Orbis provides a framework for concurrent submission and review of oncology products among international regulatory partners with the goal of increasing global access and equity. International partners include Australia, Brazil, Canada, Israel, Singapore, Switzerland, and the United Kingdom. The collaboration of Project Orbis may allow cancer patients in these other countries to receive earlier access to products, regardless of their FDA approval status. Future drug development may benefit from increased international consensus on oncology trial design and establishing greater uniformity in global standards of treatment.

**How to Apply to Your Program:** Sponsors may request that Project Orbis be used for their application. Note that participation in this initiative is based on the FDA review team's recommendation and is currently only available to oncology products. The application criteria require high-impact, clinically significant improvements in safety and efficacy compared to current therapies. Additionally, sponsors must provide a global submission plan.

[Learn more about Project Orbis](#) →



## Worldwide: A Valuable Resource

In 2022, President Joe Biden reignited the United States Cancer Moonshot initiative. The Moonshot's centerpiece goal — reducing the cancer death rate by half within 25 years — requires that trial sponsors take advantage of all available resources to enhance oncology drug development.

Worldwide stands ready to assist sponsors with developing a strategic understanding of all available tools to support a successful clinical development program. The Clinical Research Methodology team, led by Worldwide's Chief Medical and Scientific Officer and founder, Michael Murphy MD, PhD, provides strategic scientific, medical, and operational support across all phases of clinical development.

This team offers expertise in program de-risking initiatives through multi-domain portfolio reviews, fit-for-purpose assessment creation, and bespoke commercialization initiatives. Additionally, team members can assist with the creation and review of necessary regulatory documents for formal FDA meetings and IND submissions. Whether you're in IND-enabling research or coordinating a multi-regional registrational study, the Clinical Research Methodology team offers a collaborative partnership for success.

Contact us for clinical research support →