



Benefits of Orphan Drug Designation By The Numbers

Patient Population

Less than 200,000



Drugs (including biologics) for the prevention, diagnosis, or treatment of diseases or conditions affecting fewer than 200,000 persons in the US¹



5,000

The number of new drugs granted ODD since 1983.²



~7,000

The number of different rare diseases known today, with many more to still be identified.³



7 years

The possible length of market exclusivity granted upon ODD approval.⁴



25%

Potential to receive a 25% sponsor tax credit for some clinical trial costs for qualified testing.⁵

Hereditary angioedema, cystic fibrosis, childhood acute lymphoblastic leukemia, and sickle cell anemia. Diseases in which the most significant advancements have been made since introduction of the Orphan Drug Tax Credit (ODTC).⁶



Oncology, neurology, and infectious diseases

Top three therapeutic areas impacted by ODD.⁷



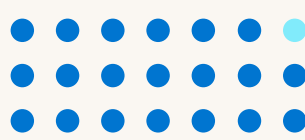
33%

The percentage of drugs that would not receive ODD over the next 10 years without the ODTC.⁸



80

The number of products approved since establishment of the FDA's Orphan Products Grants Program.⁹



>20

of Orphan Drug Designations Syner-G has helped get granted by FDA's Office of Orphan Products Development (OOPD).

Syner-G Can Help

Syner-G supports life science organizations across the scientific and regulatory continuum from concept to commercialization.

With deep expertise in product development, process scale-up and global regulatory affairs, Syner-G offers a full complement of product development, quality, and regulatory services across the spectrum of strategy, execution and management, and submission support, seamlessly acting as an extension of the partner organization.

SOURCES

- ¹ <https://www.fda.gov/media/83372/download>
- ² <https://ojrd.biomedcentral.com/articles/10.1186/s13023-021-01901-6>
- ³ <https://www.appliedclinicaltrials.com/view/rare-diseases-meeting-unique-challenges-orphan-drug-development>
- ⁴ <https://everylifefoundation.org/press-release-senate-introduces-the-open-act/>

- ⁵ <https://rarediseases.org/assets/files/white-papers/2015-06-17.nord-bio-ey-odtc.pdf>
- ⁶ <https://ojrd.biomedcentral.com/articles/10.1186/s13023-021-01901-6>
- ⁷ <https://ojrd.biomedcentral.com/articles/10.1186/s13023-021-01901-6>
- ⁸ <https://ojrd.biomedcentral.com/articles/10.1186/s13023-021-01901-6>
- ⁹ <https://www.fda.gov/industry/medical-products-rare-diseases-and-conditions/orphan-products-grants-program>