Clinical Trials for TED Teprotumumab and Beyond

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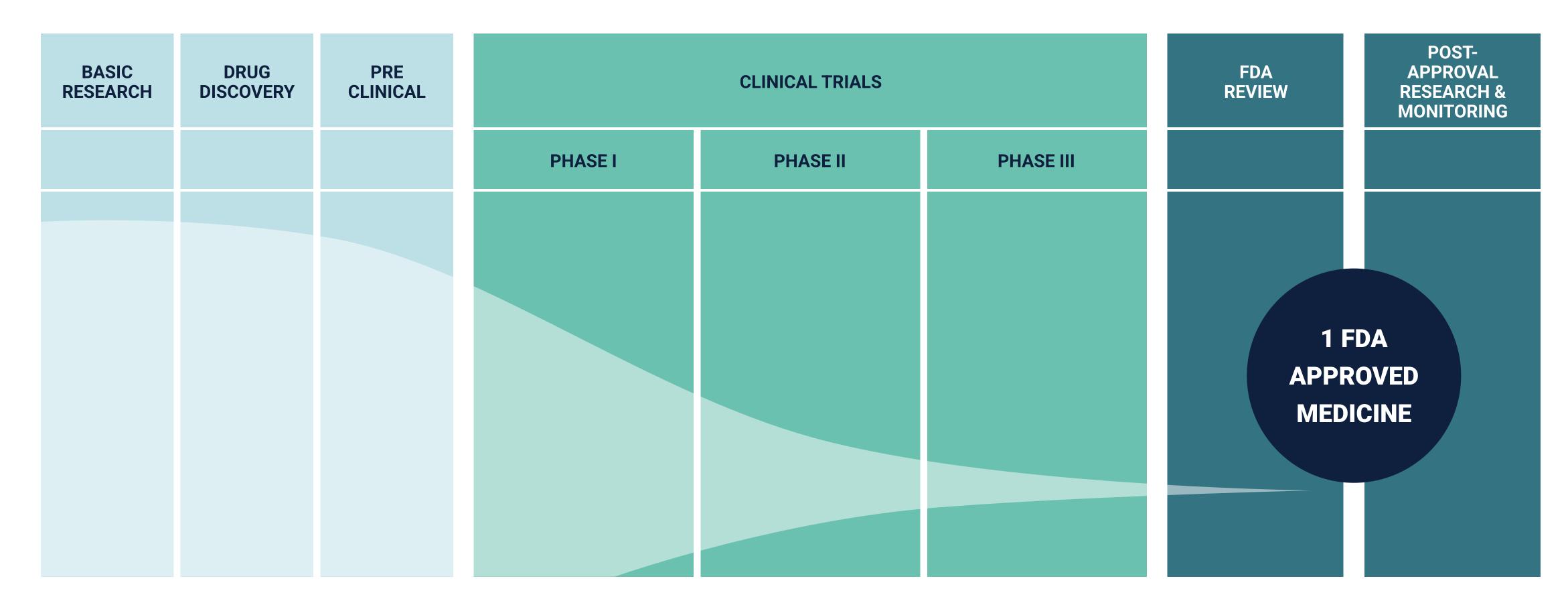
Kahana Oculoplastic and Orbital Surgery Corewell Beaumont Royal Oak



What Are Clinical Trials?

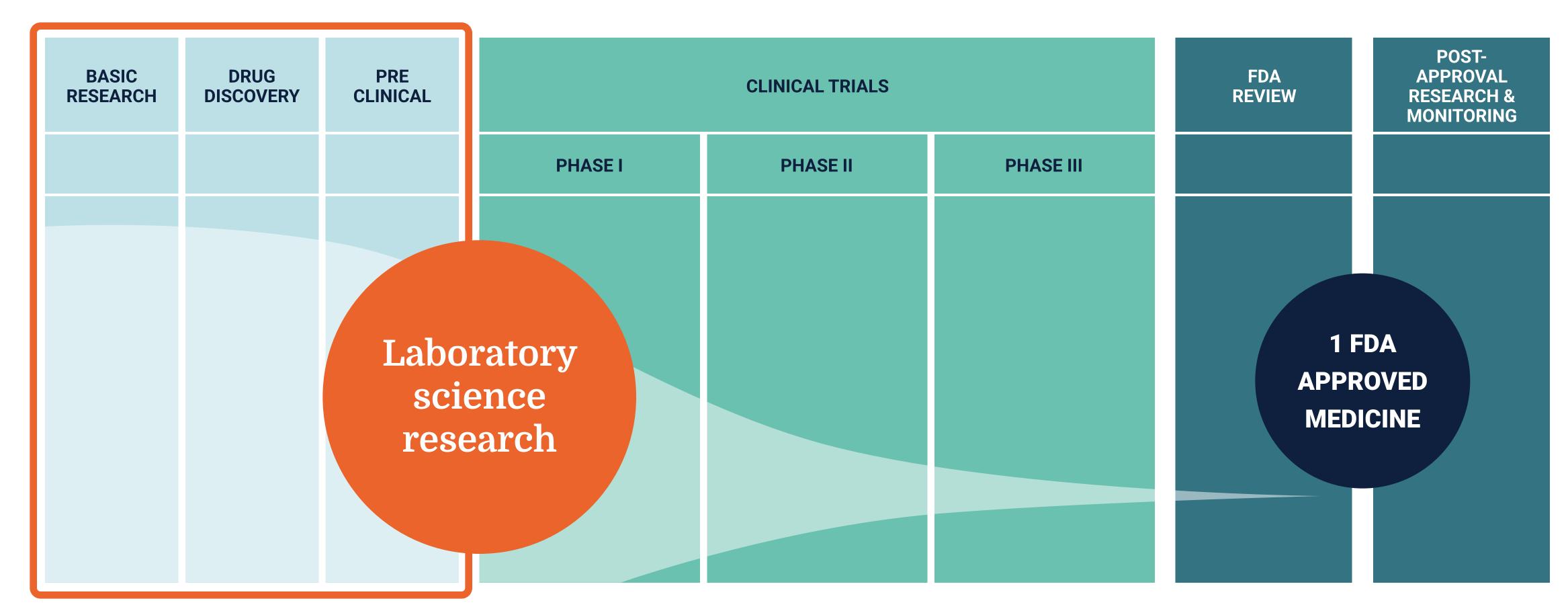
- Voluntary research studies which investigate a medical, surgical, or behavioral intervention
- National Institute of Health (NIH) and US Food & Drug Administration (FDA) have rigorous guidelines and rules for clinical studies
- Sponsored by organizations or individuals, and conducted in various healthcare sites





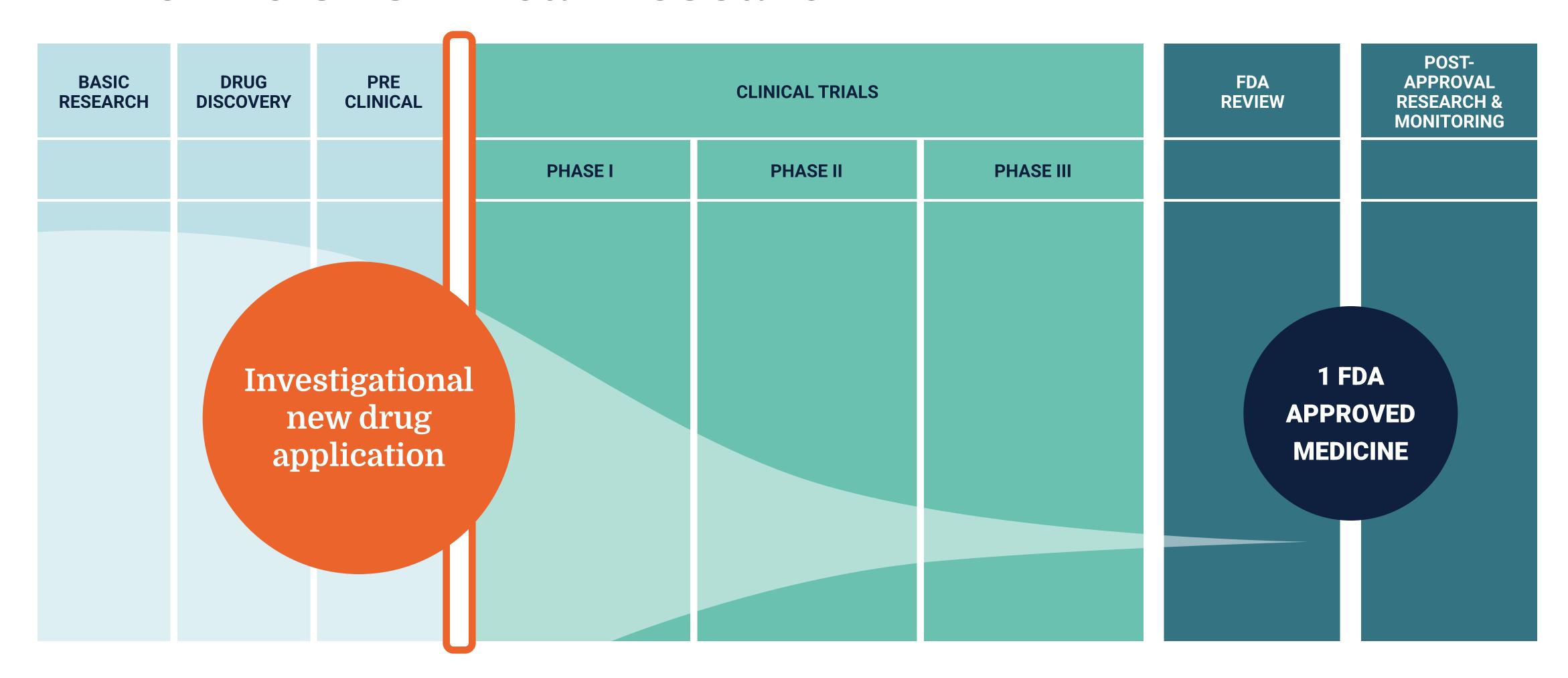
Source: https://phrma.org/en/policy-issues/Research-and-Development-Policy-Framework/Clinical-Trials



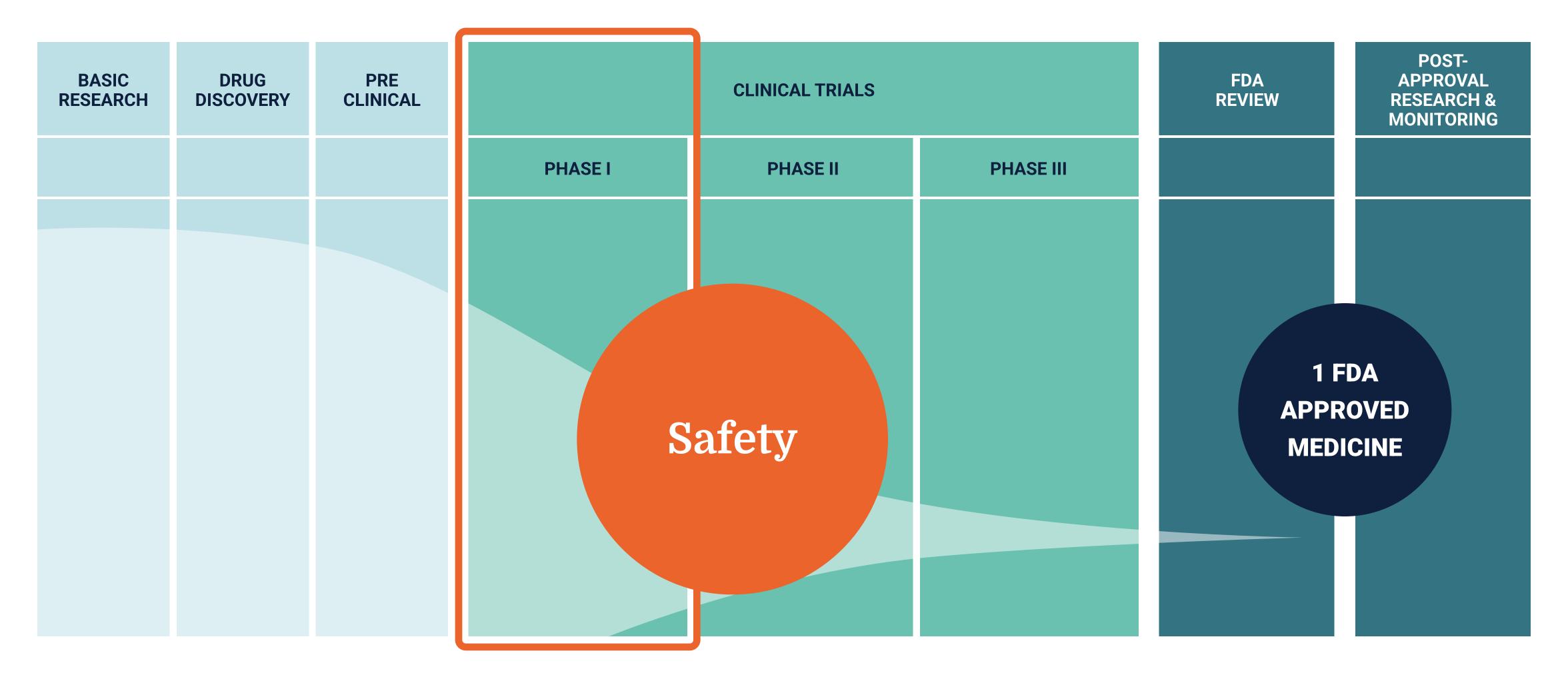


Source: https://www.tedimpact.com/thyroid-eye-disease-symptoms/pathophysiology

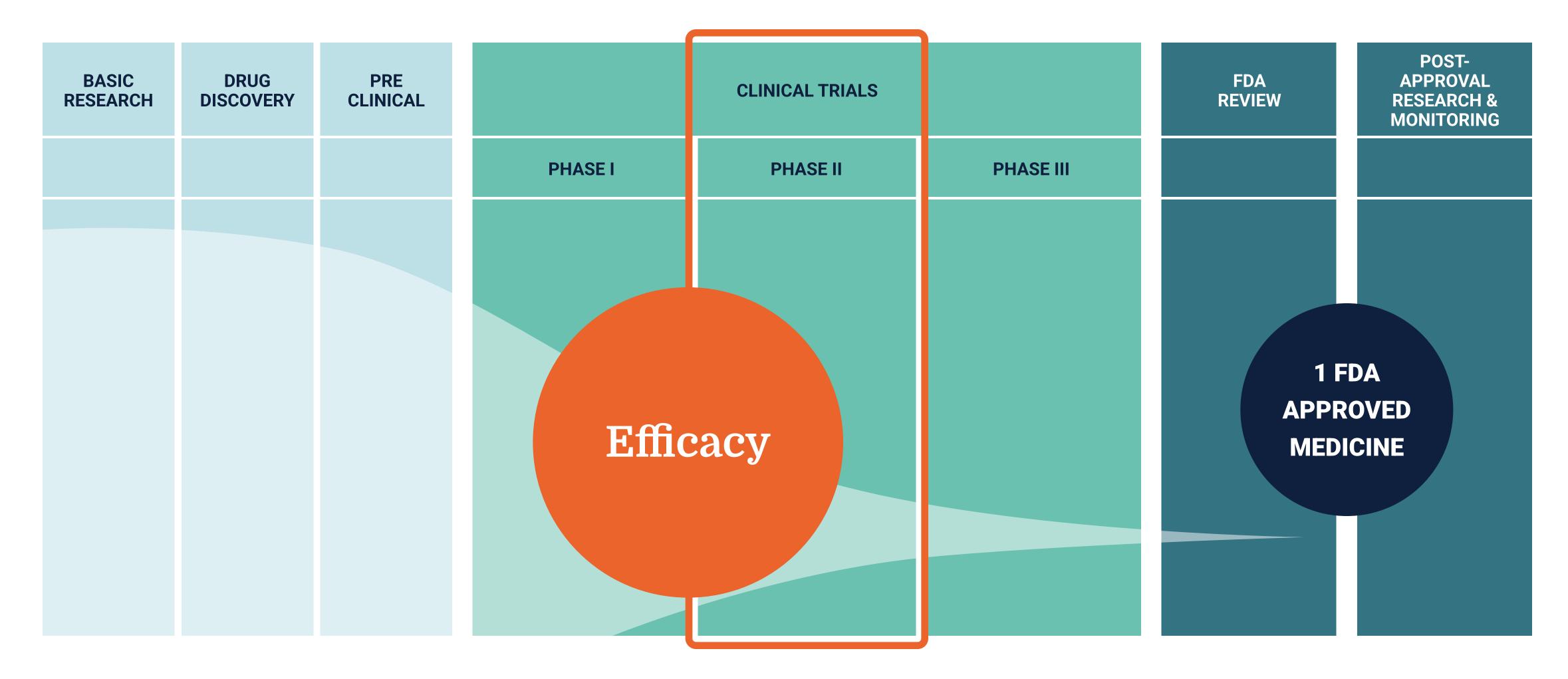




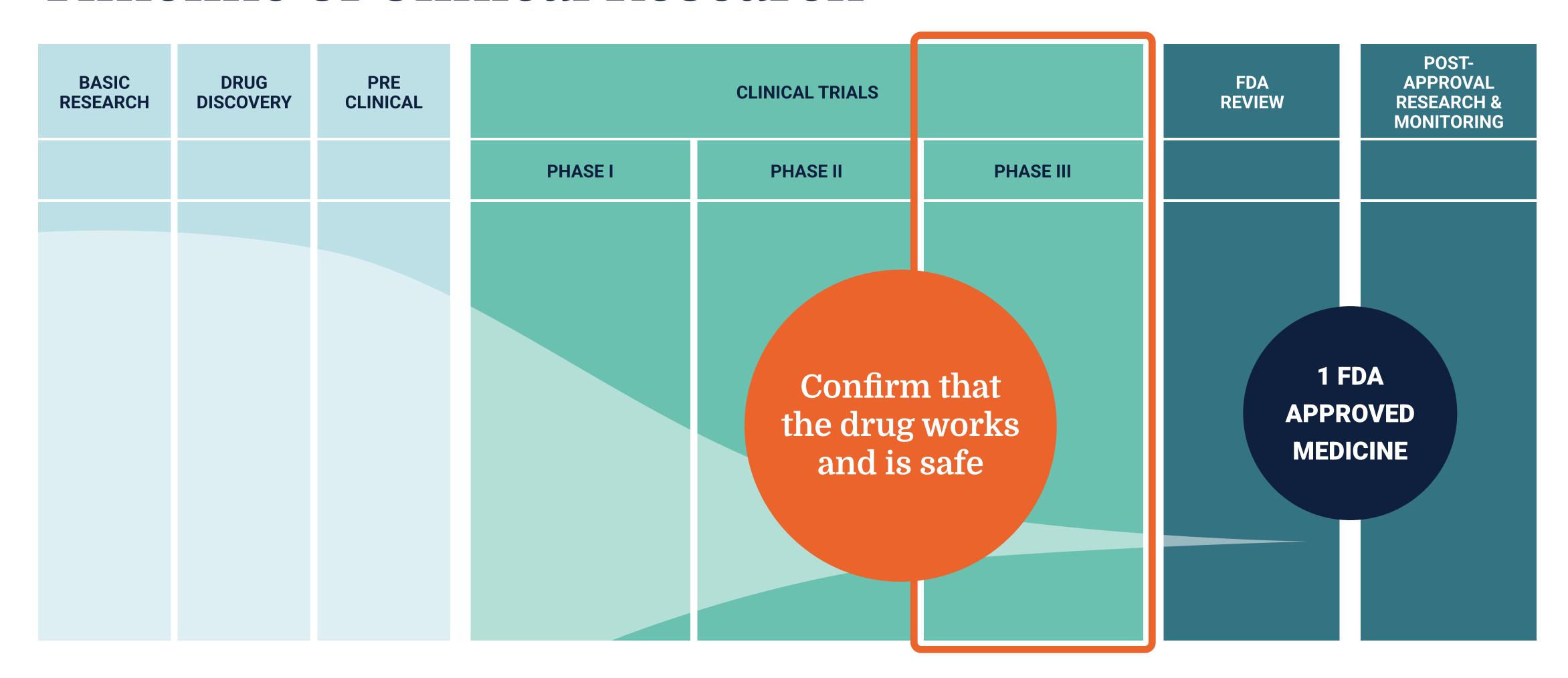




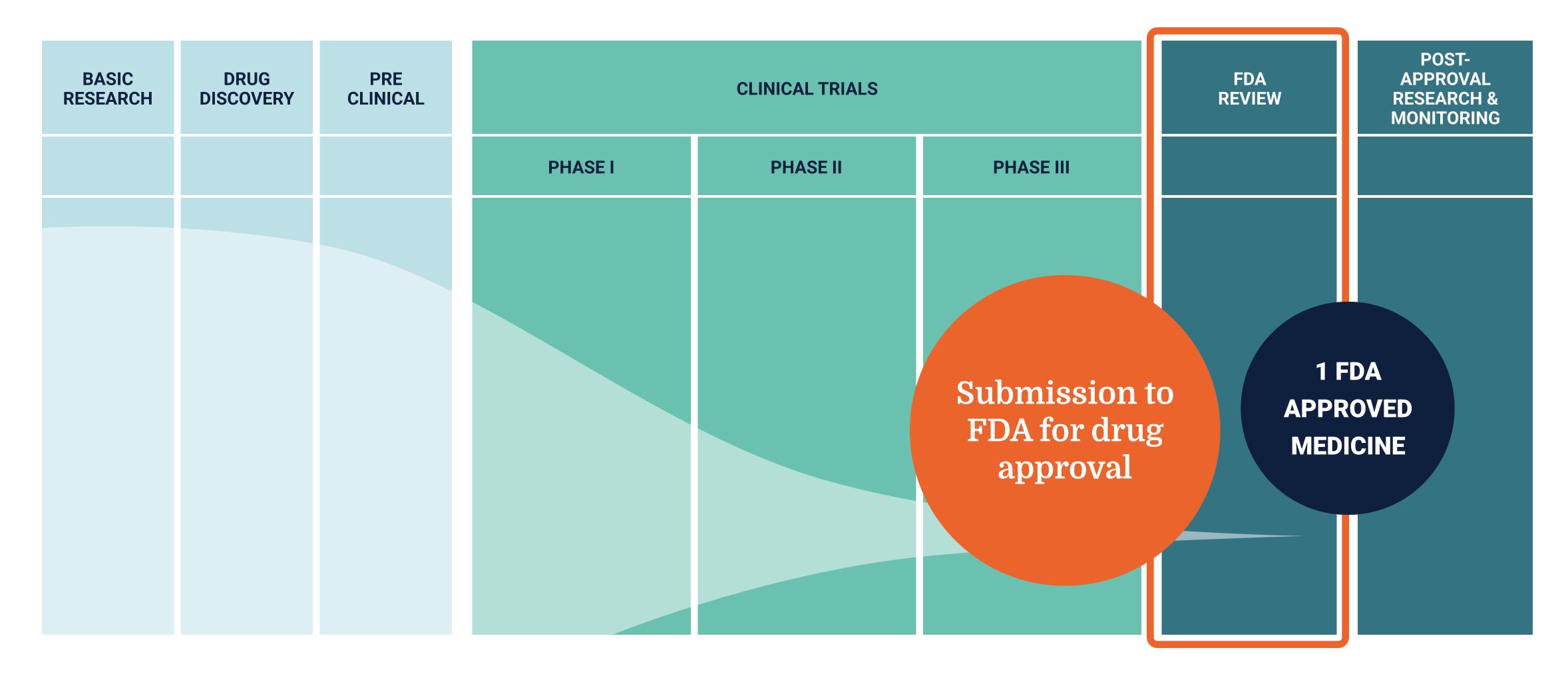




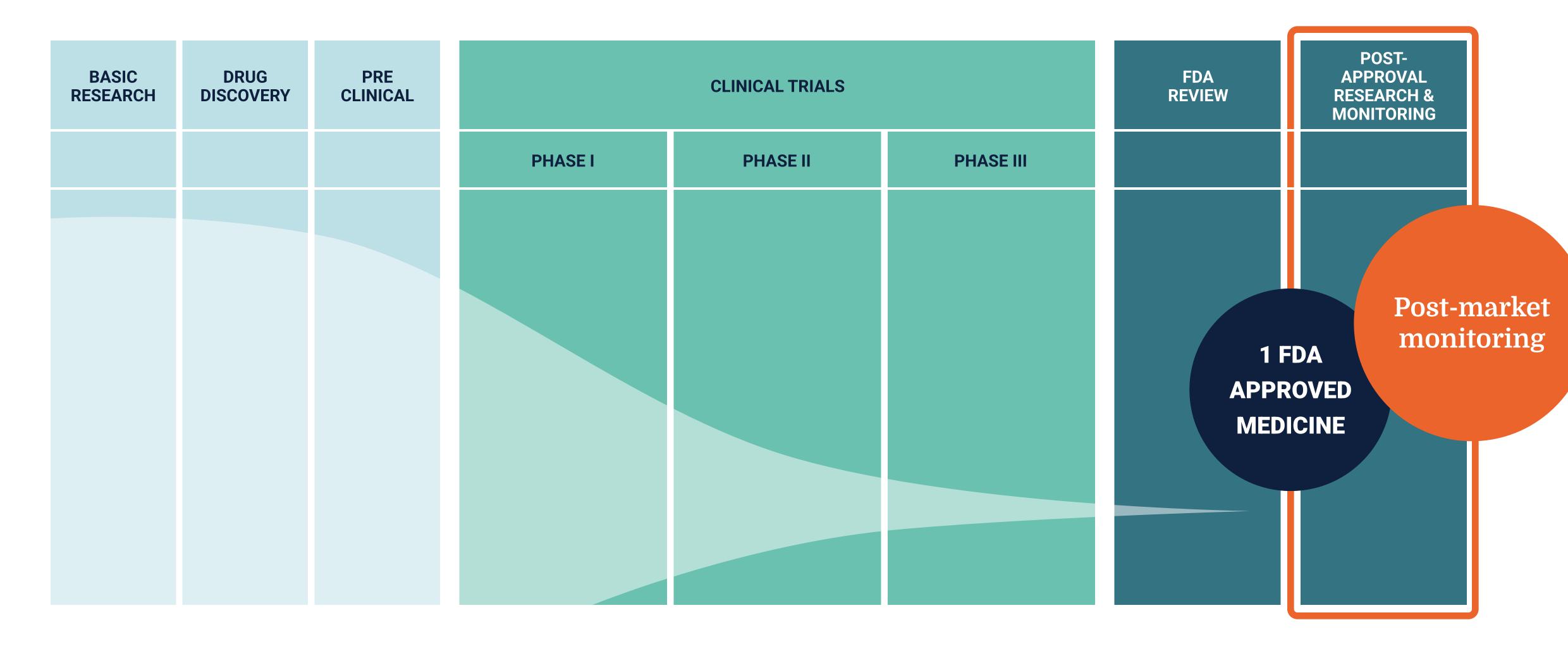




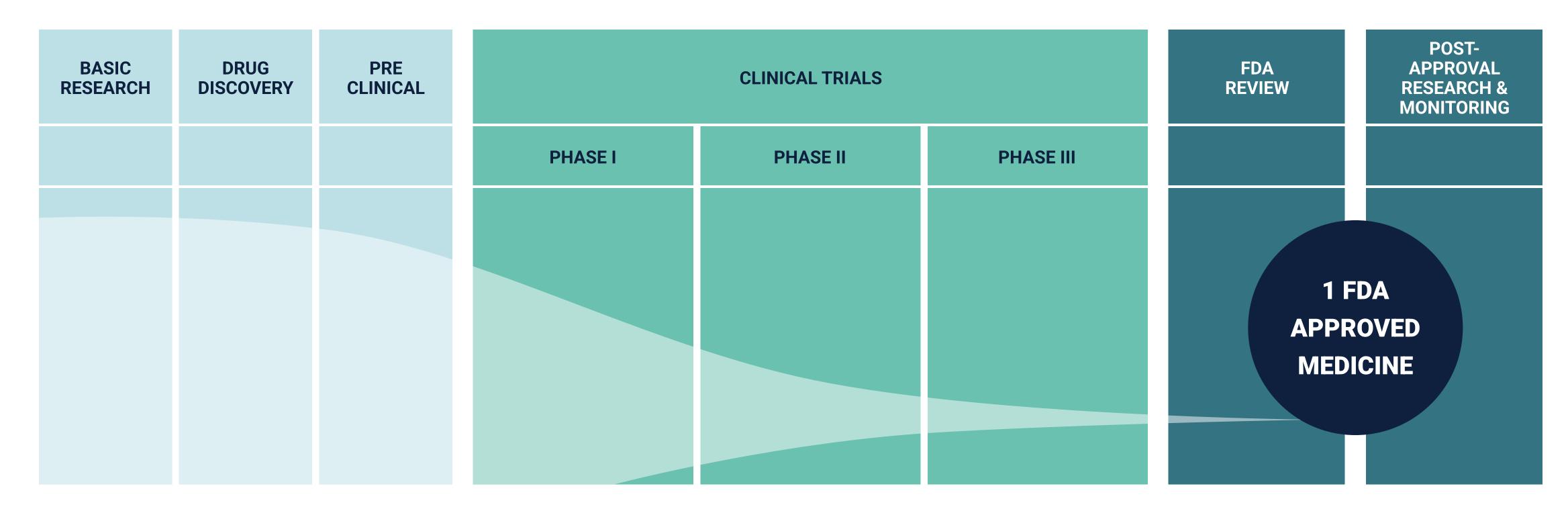








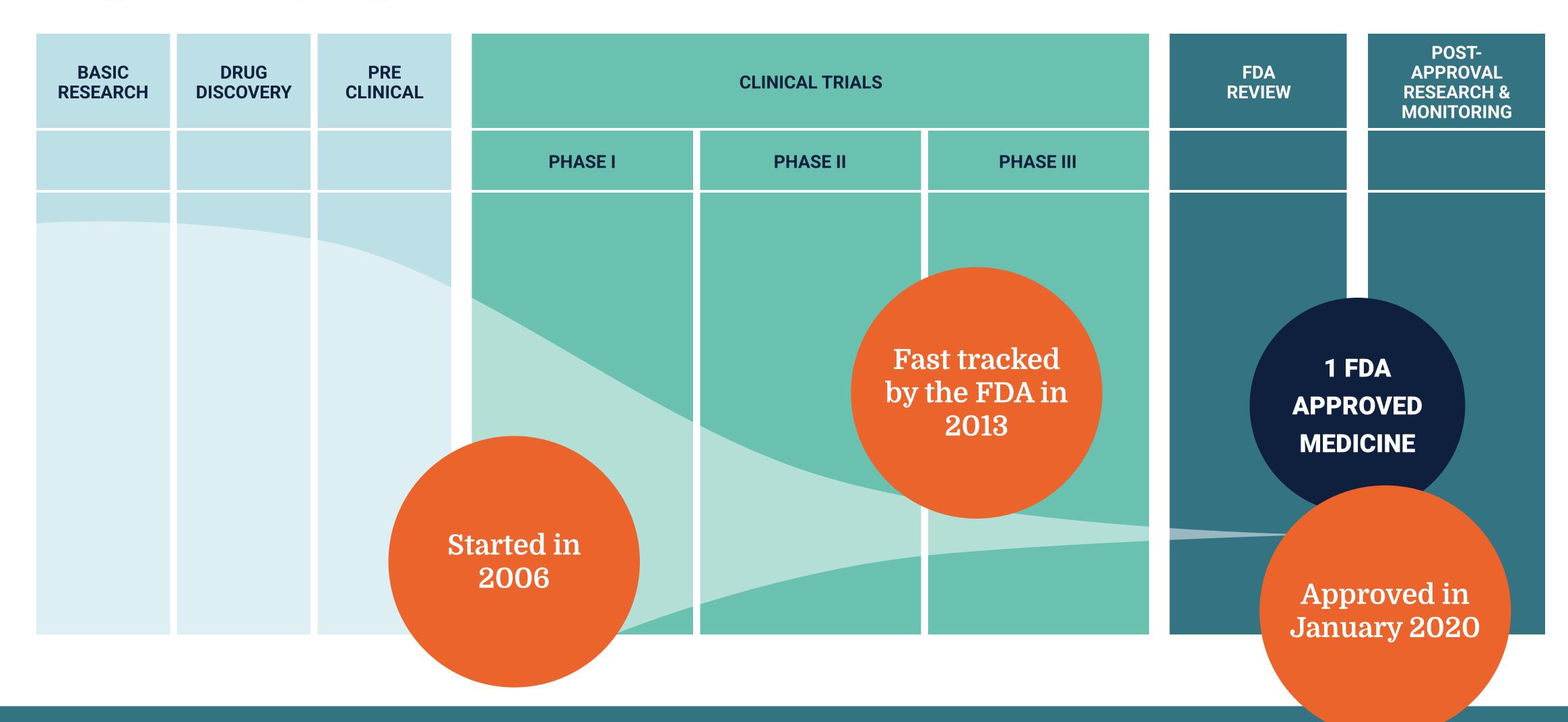




- Only 1 in 5,000 compounds tested make it to drug approval
- Process takes ~15 years
- Cost \$1.1 \$2.6 billion for each approved drug

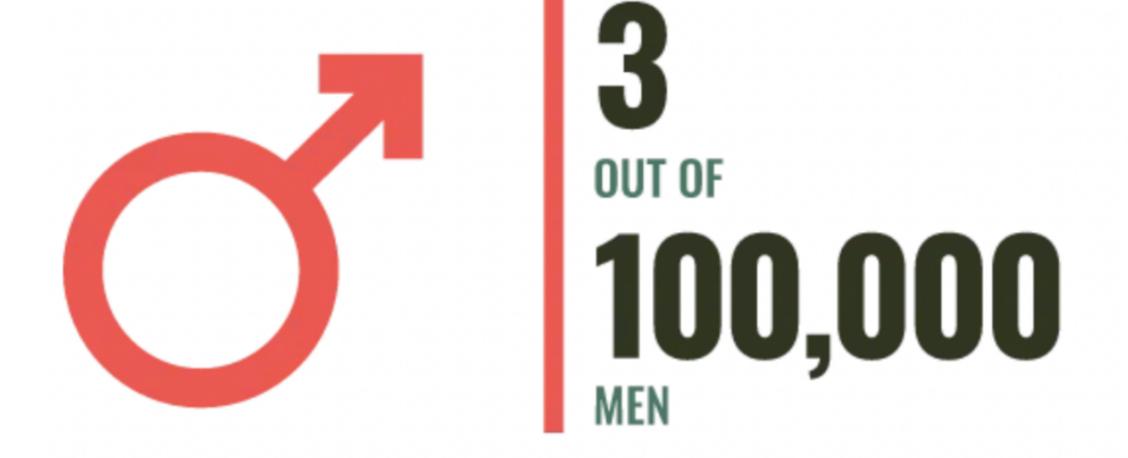


Tepezza (Teprotumumab)



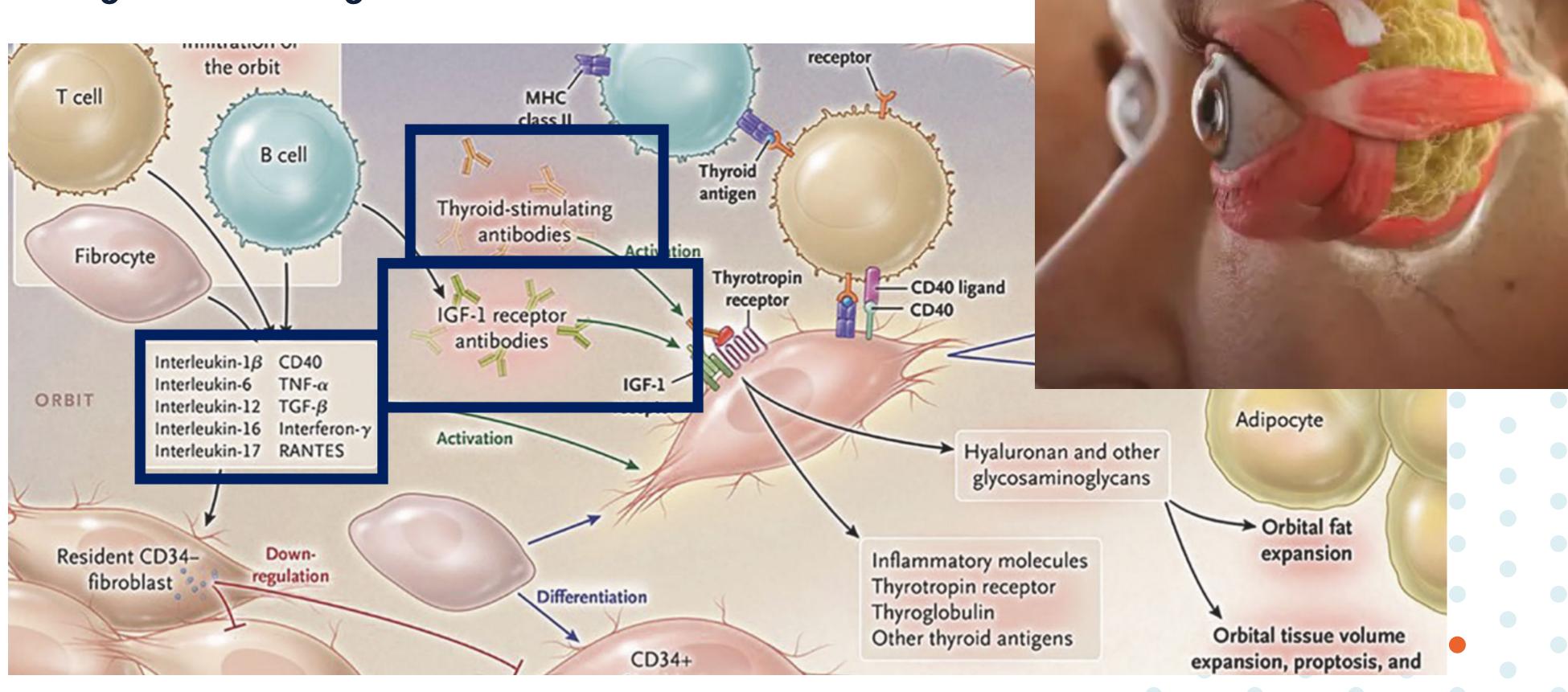


Annual incidence of TED⁴



16 OUT OF 100,000 WOMEN

There is an unmet need for disease-modifying treatments with an optimal safety profile and long-term benefits.





TED Pipeline

| Name | Sponsor | Target | Route of Administration | Stage | Clinical Trial ID |
|------------------------|-----------------------|-----------|-------------------------|----------------|-----------------------------|
| Teprotumumab (Tepezza) | Horizon | IGF-1R | IV Infusion | Post-marketing | NCT04583735, NCT05002998 |
| VRDN-001 | Viridian Therapeutics | IGF-1R | IV Infusion | Phase 3 | NCT05176639, NCT06021054 |
| Lonigutamab (VB421) | ValenzaBio/Acelyrin | IGF-1R | SQ | Phase 1/2 | NCT05683496 |
| Batoclimab | Immunovant | IgG1 FcRn | SQ | Phase 3 | NCT05524571, NCT05517421 |
| Linsitinib | Sling Therapeutics | IGF-1R | Oral | Phase 2b | NCT05276063 |
| Cosentyx | Novartis | IL-17A | SQ | Phase 3 | NCT04737330 |
| TOUR006 | Tourmaline Bio | IL-6 | SQ | Phase 2b | NCT06088979 |
| LASN01 | Lassen Therapeutics | IL-11 | IV infusion | Phase 1 | NCT05331300 |



TED Pipeline

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|-------------------------|-------------------------------|-----------------------------|-------------------------|-----------|-------------------|
| Aflibercept | MEEI | VEGF | Sub-tenon | Phase 2 | NCT04311606 |
| Satralizumab | Hoffmann-La Roche | IL-6 | SQ | Phase 3 | NCT05987423 |
| Bimatoprost | Johns Hopkins University | Prostaglandin receptor | Ophthalmic drop | Phase 1 | NCT03708627 |
| HBM9161 | Harbour BioMed | IgG-FcRn | SQ | Phase 2/3 | NCT05015127 |
| Anti-thymocyte Globulin | Medical University of Silesia | Thymocyte globulin | IV | N/A | NCT05199103 |
| Tocilizumab | Sun Yat-set University | IL-6 | IV | Phase 2 | NCT06087731 |
| Simvastatin | Lund University | HMG-CoA reductase inhibitor | Oral | Phase 3 | NCT03131726 |
| IBI311 | Innovent | IGF-1R | IV | Phase 2/3 | NCT05795621 |

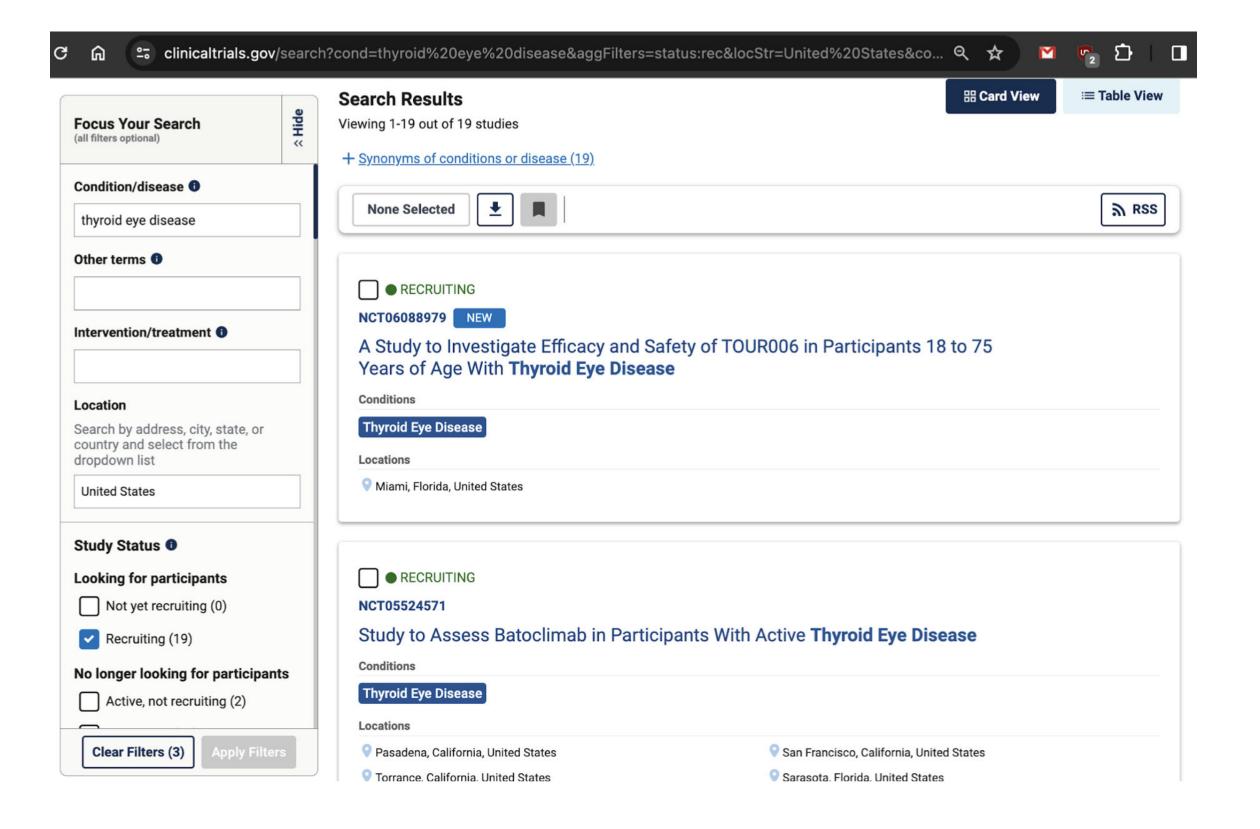


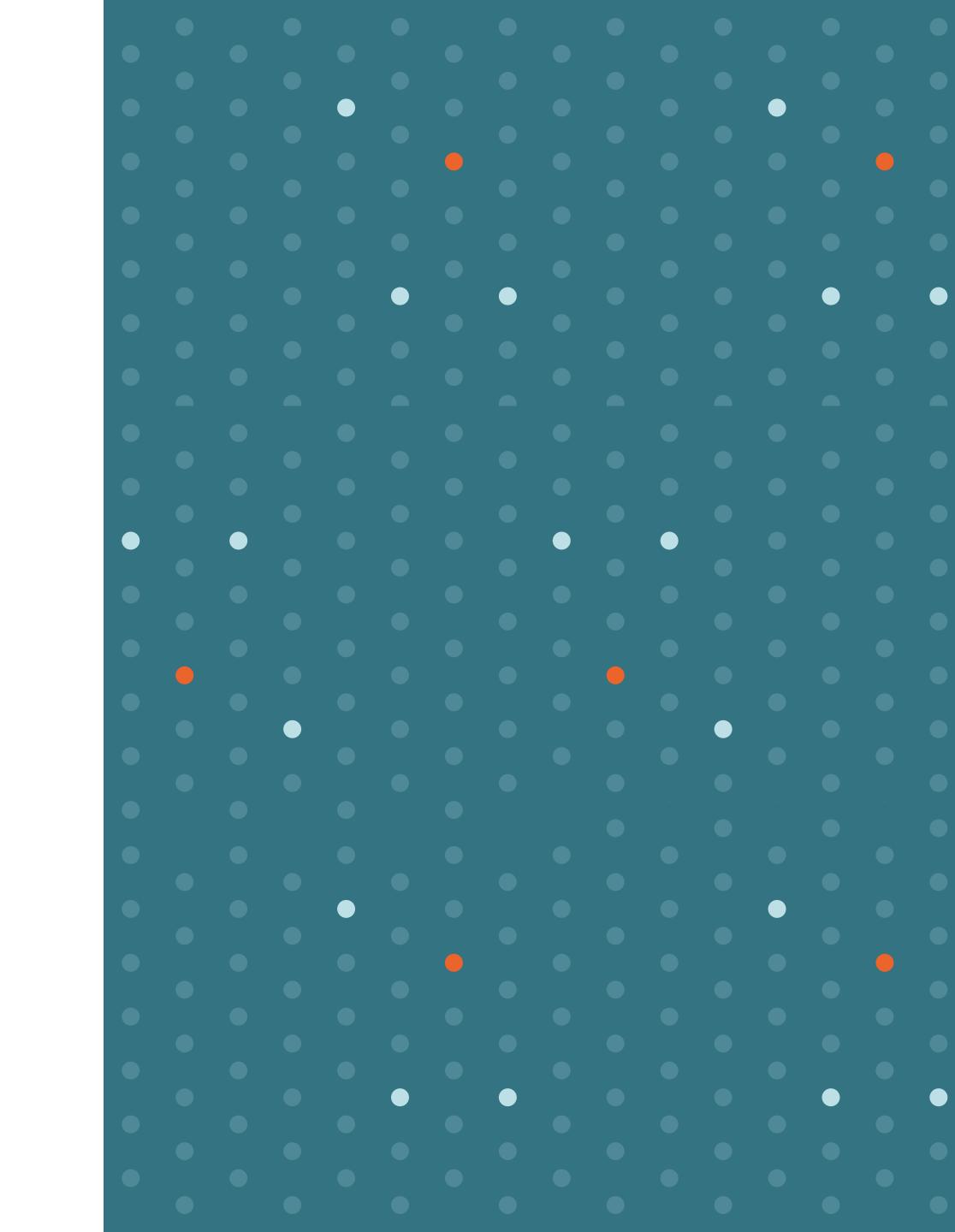
Why Do Patients Participate In Clinical Trials?

- Gain access to new treatments not available to the public
- None of the standard available treatments have worked or have resulted in intolerable side effects
- Insurance
- Contribute to advancing scientific discovery and help other people



National Institute of Health: www.ClinicalTrials.gov





Thank You!

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