Accelerating Complex Drug Development through the 505(b)(2) Pathway

Features of the 505(b)(2) Pathway Driving Industry's Interest

	Studies	Market exclusivity	Timing for Approval	Cost of Drug Development	Clinical trials, Non-clinical / Toxicology data
505(b)(1)	Full	5 years	8–15 years	$500 m – 2b	Yes
505(b)(2)	Partial	3–5 years	2–5 years	$3 m – 7 m	Maybe

Key Challenges Associated with Traditional Pathway

- Need for sophisticated planning and development process
- Need for expertise knowledge in determining measurements and studies required to demonstrate therapeutic equivalence
- Difficult to establish equivalence, safety and efficacy endpoints of therapy
- Challenging time-consuming and expensive to develop
- Lack of clear regulatory guidelines for approval
- Identification of targeted markets and indications to address unmet patient need

USFDA Approvals Through the 505(b)(2) Pathway as of May 2024: Key Drugs

- Irinotecan Liposomal
- Budesonide Oral Suspension
- Iloprost
- Clobetasol Propionate 0.05%
- Macitentan/Tadalafil
- Risperidone Extended-Release Injection
- Mycophenolate Mofetil Oral Suspension
- Naloxone Hydrochloride Nasal Spray
- Diazepam Buccal Film

Veeda Group's Capabilities in Supporting 505(b)(2) Applications

Non-Clinical / Pre-Clinical Studies	Clinical Studies
◉ In Vitro studies ◉ In Vitro PD studies ◉ In Vivo PK/PD studies ◉ In Vivo Toxicology studies: • Repeat dose toxicity studies (14/28/90 days etc.,) • DART studies • Genotox studies	◉ Single & multiple dose BA/BE ◉ Dose proportionality ◉ Pharmacokinetics/Pharmacodynamics ◉ Food effect ◉ Safety/ efficacy studies ◉ Drug Interaction ◉ Single Ascending Dose/ Multiple Ascending Dose

Proficiency in **More Than 10 Therapy** Areas Including Psychiatry, Endocrinology, Respiratory, Dermatology and others

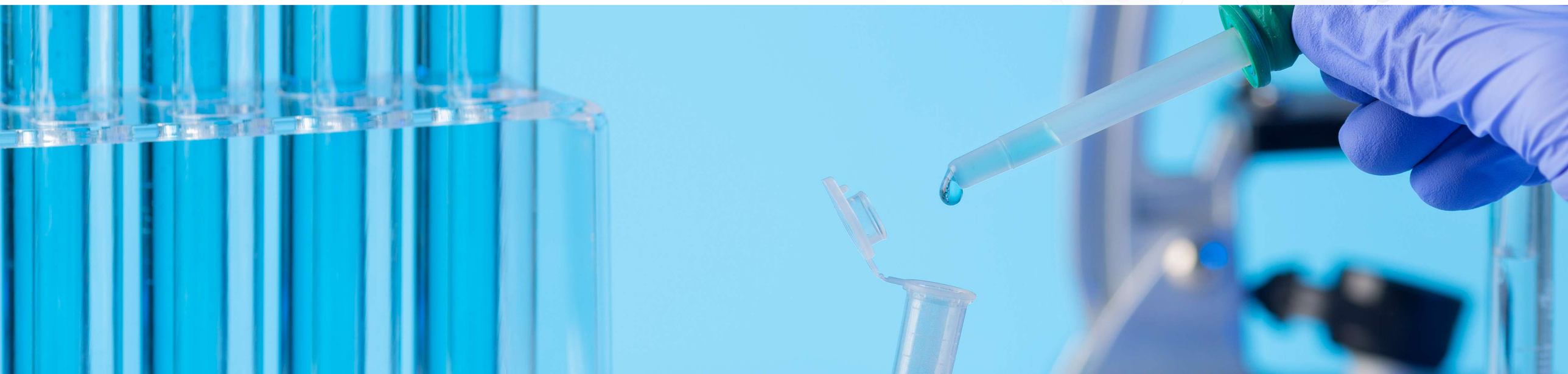
Veeda Group's proficiency in Navigating Regulatory Approvals through 505(b)(2) Pathways:

Successfully Executed **45** Studies

Completed **14** Complex Studies

Enrolled **1300+** Volunteers

Collaborated with **25+** Global Sponsors



Wide Experience across Different Formulations:

- Tablet
- Capsule
- ODT (Orally Disintegrating Tablet)
- Sublingual Spray
- Granules Sachet
- Oral Solution
- Solution
- Ophthalmic Solution
- Rectal Suspension
- Oral Suspension

Studies Successfully Submitted to Global Regulatory Bodies such as: USFDA, Health Canada, ANVISA, DCGI, NPRA

Veeda Group Advantage

- Skilled personnel with focus on Continuous Professional Development
- High Customer Centricity and Satisfaction
- Extensive Scientific Competence to service a Diverse client base
- One of the largest Independent Full Service CROs in India
- Global Presence in 26 Geographies Across the US, EU, and Asia-Pacific
- Robust Quality & Regulatory Compliance
- One stop solution for complex studies

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