# From Pre-IND Hurdles to Global Roadmap- FDA Success Through IND Gap Analysis

## At a glance

To advance the novel therapeutic product into the final phase of clinical development, a global pharmaceutical company required regulatory support in preparing for a pre-IND meeting with the U.S. FDA and in conducting a gap analysis of the IND documentation

## The Challenge

01 Need for specialized regulatory & clinical expertise

02 Preparing for a successful FDA pre-IND meeting

03 Ensuring IND readiness through gap analysis

## COD's Solution

### Pre-IND & IND Support

- Pre-requisites assessment for pre-IND meeting
- FDA electronic submission access setup
- Pre-IND package publishing & submission
- FDA communications & IND lifecycle support

## IND Gap Analysis

- Regulatory research & interpretation
- Administrative & technical completeness checks
- Cross-module consistency review
- Clinical data assessment by clinical experts at COD
- eCTD-aligned structure & document placement
- Strategic use of Real-World Evidence (RWE)
- Regulatory roadmap for order and timeline to submit iPSP, SPA and IND

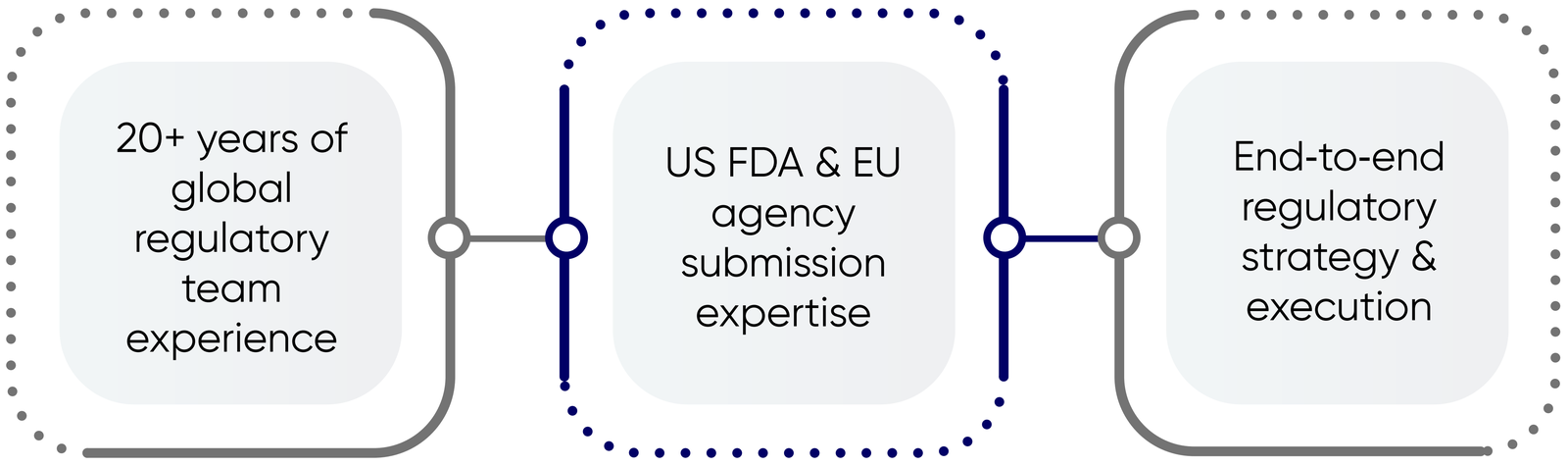
# The Outcome

- Productive & successful FDA pre-IND meeting
- IND documentation aligned with FDA compliance expectations

### Expanded Engagement Included:

- Additional pre-IND & IND filings
- Ongoing IND maintenance
- Regulatory support across multiple global markets including Europe


# Why COD?




Need help with Pre-IND or IND readiness? **Let's talk.**